## UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

Pharmac	cyChecker.com LLC,	)			
Alliance Center f	Plaintiff, v.  I Association of Boards of Pharmacy, e for Safe Online Pharmacies, for Safe Internet Pharmacies Ltd., hip for Safe Medicines, Inc.  Defendants	) ) ) ) ) No. 7:19-cv-07577-KMK ) ) Honorable Kenneth M. Karas ) ) )			
	DEFENDANT NABP'S AME	NDED COUNTERCLAIMS			
INTROI	DUCTION	2			
THE PA	ARTIES	6			
JURISD	ICTION AND VENUE	7			
FACTU	AL ALLEGATIONS	7			
I.	PCC's Commercial Mission	17			
the	Legality, Safety, and Other Material Attr	Claims About its "Accredited" Pharmacies and ibutes of the Drugs they Sell to Unwitting U.S.			
A. the		out the Legality of Personal Importation and uticals and FDA-Approved Pharmaceuticals 23			
B.	PCC Hides that the "Pharmacy" Websit	tes It Links to Are Not Pharmacies at all 30			
C.	Statements that Mislead Consumers on Price				
D.	Statements that Mislead Consumers Ab	out the Origin of the Drugs They are Buying 39			
		the Safety and Trustworthiness of PCC's46			
III.	PCC's False and Misleading Claims Al	oout NABP62			
IV.	Harm to NABP and Consumers, Include	ing in Washington, D.C 69			
Counter	claim	73			
REQUE	ST FOR RELIEF				
DEMAN	ND FOR JURY TRIAL				

Defendant/Counterclaim-Plaintiff National Association of Boards of Pharmacy ("NABP") for its counterclaims against Plaintiff/Counterclaim-Defendant PharmacyChecker.com LLC ("PCC") alleges as follows:

#### INTRODUCTION

- 1. PCC is engaged in the business of misleading consumers about the safety, legality, efficacy, and pricing of unlawfully imported drugs from foreign "pharmacy" affiliates that are subject to PCC's "verification program." PCC directly and indirectly profits from misleading consumers and facilitating consumer purchases of these drugs from PCC's affiliate suppliers.
- 2. As part of this campaign, PCC has engaged in false and misleading public statements and advertising to misrepresent the character of its "verified" pharmacies and the safety and efficacy of the goods they sell.
- 3. By way of example only, once a consumer visits the PharmacyChecker.com site, PCC immediately encourages the consumer to search for where and how their prescriptions can be filled at what PCC leads consumers to believe are "pharmacies" that are, in reality, nonpharmacy "intermediaries" that purport to offer the lowest drug prices possible. PCC tells consumers that these pharmacy intermediaries, which are in fact supplied by yet other hidden dispensing pharmacies, are safe, that they are regulated by government entities, that the drugs they sell are equivalent to or the same as FDA-regulated drugs, and that any violations of the law are

equal and, as part of these Counterclaims, NABP asserts that PCC's description of its program is misleading to consumers in a way that is harmful to consumers and NABP.

<sup>&</sup>lt;sup>1</sup> PCC uses words like "verified" and "accredited" to describe companies that pay it money in exchange for access to U.S. consumers seeking to buy foreign drugs. While NABP may use or repeat the words "verified" and "accredited" (with or without quotations) throughout these Counterclaims, NABP's use of such terms in connection with PCC's business model is not intended to suggest that NABP believes PCC's program is robust, credible, or ensures patient safety. And while NABP provides its VIPPS (now known as Digital Pharmacy Accreditation) verification and accreditation program, PCC's verification/accreditation program is unlike and in no way a substitute for NABP's VIPPS/Digital Pharmacy Accreditation program. Not all verification and accreditation programs across the globe are

mere technicalities and they will not face sanction. Each of these statements is false and misleading.

- 4. American consumers who encounter PCC's websites, including thousands of consumers of PCC's services who reside in Washington, D.C., are and/or are likely to be deceived by PCC's false and misleading statements and indeed some rely on these statements to make purchases through PCC's "verified" pharmacy intermediaries and other "accredited" anonymous pharmacies. All or virtually all of these purchases, which PCC facilitates through its PharmacyChecker.com and now discontinued blog site, violate state and/or federal law.
- 5. PCC has unilaterally determined and often announces as part of its commercial speech—and contrary to state and/or federal law—that these foreign drug suppliers are safe if they require a prescription, or if they include a consultation from a "pharmacist" licensed in some foreign jurisdiction, or if purchases are only for a limited 90-day supply or less and if they buy from a PCC-verified pharmacy. Under the circumstances relevant to these Counterclaims and this lawsuit, these are not representations that PCC can accurately make to American consumers. PCC is not a substitute for the FDA or state regulators. PCC simply lacks the resources of the United States government to ensure the safety of what is an undeniably vast and complex drug supply. In fact, while PCC publicly touts to U.S. consumers that its affiliated "verified" pharmacies are safe, PCC testimony explicitly disclaims this—admitting that "I don't know that it was anyone's job at PharmacyChecker to verify that online pharmacies were safe" and

  And PCC's thicket of false and misleading

And PCC's thicket of false and misleading statements and half-hearted, conflicting, and/or confusing purported disclaimers are an affirmative danger to consumer health and safety.

- 6. PCC has also directly disparaged NABP, which independently works to support a vibrant marketplace for the safe, responsible, and lawful practice of pharmacy. PCC has used its online blog to make false, misleading, and disparaging statements about NABP while, and for the purpose of, deliberately steering more and more consumers to PCC in order for them to engage in commercial transactions with PCC's affiliates via PCC's website and blog.
- 7. For example, in a recent PCC blog post, PCC falsely alleged that NABP and pharmacies NABP accredits "are complicit in the deaths of hundreds of thousands of Americans from opioid drugs" and that NABP "ignored the opioid crisis." It then provided a link to consumers to buy pharmaceuticals through PCC's "verified" pharmacies.
- 8. PCC has also falsely claimed that NABP was complicit with wholesale drug distributors in the wholesalers' alleged role in the opioid crisis because of alleged failings in NABP's wholesale accreditation programs. Again, PCC then provided consumers with a link to "find low drug prices," facilitating purchases through PCC's "verified" pharmacies. PCC's commercial speech is intended to enrich PCC to the detriment of NABP and patient safety.
- 9. PCC alleges that NABP, "[t]hrough its Verified Internet Pharmacy Practice Sites (VIPPS) program, as well as its '.pharmacy' Verified Websites program and Internet Drug Outlet Identification Program, is a direct competitor of PharmacyChecker.com in the market for online pharmacy accreditation and information."
- 10. PCC explicitly compares its "verification tool" to NABP's pharmacy program by positioning it as a "critical alternative to the National Association of Boards of Pharmacy (NABP) dot pharmacy (.pharmacy) program, which was funded by pharmaceutical companies and excludes safe international online pharmacies, including licensed Canadian pharmacies, that sell to Americans." PCC offers this product comparison so that consumers believe that PCC can offer

services comparable to NABP and government regulators. Just as PCC is not a substitute for the FDA, PCC is not a substitute for NABP. To be clear, PCC is not a direct competitor of NABP in Pharmacy Accreditation Services or any other product or service.

- 11. PCC's materially false comparison of its "verification" program necessarily diminishes NABP's accreditation program in the minds of consumers.
- 12. NABP, as part of its Digital Pharmacy Accreditation Program (formerly known as VIPPS), accredits the digital pharmacy practices of licensed pharmacy practices that, as a baseline requirement, comply with U.S. state and federal law. NABP thus accredits domestic pharmacies that supply legal prescription pharmaceuticals to U.S. consumers. PCC offers an entirely different service, where it gives its stamp of approval to websites that meet PCC's own esoteric—and, as described below, false and misleading—standards. PCC "verifies" foreign online pharmacies and online platforms masquerading as pharmacies that list foreign drug prices and sell foreign, unapproved drugs to U.S. consumers in violation of U.S. state and federal laws. While PCC and NABP thus offer different products, PCC intentionally confuses consumers by incorrectly equating the services and, in fact, stating that PCC offers services superior to NABP's accreditation program.
- 13. PCC's campaign has caused NABP to suffer damage, including damage to its reputation, business, and good will. As a result of PCC's disparagement, NABP has, among other things, incurred damages including those relating to spending money to defend its reputation and diverting other scarce resources, assets, and the attention of key personnel away from NABP's core missions and toward responding to and combatting PCC's false and disparaging statements specifically targeting NABP, and the damage such false and disparaging statements have caused NABP to suffer.

- 14. PCC's unlawful and dangerous campaign, including its false and misleading commercial speech, is also consumer-oriented and has caused and, if left unchecked, will continue to cause damage to consumer health and safety. PCC has also caused consumers to unwittingly incur significant legal and financial risks, exposure, and liability. NABP has had to devote time and expend resources to correct these PCC-induced consumer misapprehensions.
- 15. PCC's efforts have also undercut efforts by NABP to create a vibrant marketplace for safe, lawful, legitimate online pharmacy. There are thousands of bad actors on the internet that purport to be pharmacies that are not licensed, or that dispense unregulated drugs, or that even dispense without the legal right to dispense to the consumers that they are targeting. NABP has made it its mission to support patient and prescription drug safety, including by giving consumers tools to differentiate legitimate online pharmacies that can lawfully sell to them and other websites that purport to be pharmacies but that do not comply with the laws and rules applicable to pharmacies. PCC has built its business model around blurring the line and misleading consumers about the difference between safe, lawful online pharmacies and websites that purport to be pharmacies, but pick and choose which aspects of pharmacy and pharmaceutical regulation that they comply with. NABP has had to devote time and money to correct consumer misapprehensions about NABP and its accreditation program caused by PCC, and to protect patient safety by ensuring the existence of a legal, safe marketplace for online pharmacy for those consumers who do choose to purchase pharmaceuticals online.

#### **THE PARTIES**

16. Counterclaim-Plaintiff National Association of Boards of Pharmacy is organized under the corporate laws of the state of Kentucky and has its principal place of business in the State of Illinois.

17. Counterclaim-Defendant PharmacyChecker.com LLC is a limited liability company organized under the corporate laws of the state of New York and with its principal place of business in the County of Westchester, New York.

#### **JURISDICTION AND VENUE**

- 18. This is an action in which NABP seeks economic and injunctive relief from PCC arising under District of Columbia statutory law. PCC's unlawful acts have harmed the goodwill of NABP and caused real economic damage and harm.
- 19. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because there is complete diversity between the parties and the amount in controversy exceeds \$75,000. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367 as the state law claim arises out of the same transaction or occurrence as the federal claims brought by PCC so as to form part of the same case or controversy.
- 20. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(1) and (b)(2) as Counterclaim-Defendant resides in this judicial district and because, upon information and belief, a substantial portion of the events giving rise to the claim occurred in this judicial district.

#### FACTUAL ALLEGATIONS

21. PCC has engaged in two simultaneous but intertwined campaigns to mislead consumers. First, PCC has based its entire business model on affirmatively misleading consumers about the safety and legality of imported drugs sold through its website and their equivalence to FDA-approved drugs, as well as the legality, regulatory rigor, and origin of drugs sold through its website. Second, PCC has gone out of its way to directly attack and sully NABP's reputation—this is because NABP's mission (in part) to enhance and promote patient safety and when consumers do choose to buy pharmaceuticals online, enabling them to do so safely and legally, is antagonistic to PCC's business model of profiteering off of encouraging, empowering, and

facilitating the unlawful purchase of foreign drugs for personal use. PCC maximizes its commercial interest by deriding NABP and by misleading consumers into purchasing foreign drugs via PCC's website, blog, and via its affiliated drug suppliers' websites.

#### The NABP

- 22. NABP is an independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.
- 23. NABP is a 501(c)(3) nonprofit organization founded in 1904. NABP supports and works with state and jurisdictional boards of pharmacy, to protect the public health. NABP generates the majority of its revenues from a variety of programs including pharmacy licensure examinations, electronic licensure transfers, as well as pharmacy accreditation. The remainder of NABP's revenues come from state membership dues, publication fees, convention or conference registrations and contributions as well as some investment income.
- 24. NABP was initially established to assist the state boards of pharmacy in creating uniform education and licensure standards. NABP members consist of the 50 United States state boards of pharmacy, as well as the boards in the District of Columbia, Guam, Puerto Rico, the Virgin Islands, 10 Canadian provinces, and The Bahamas.
- 25. NABP supports patient and prescription drug safety through examinations that assess pharmacist competency, pharmacist licensure transfer and verification services, and various pharmacy accreditation programs. NABP has also actively participated in litigation to further the public interest in safe prescription drugs, filing amicus briefs on topics including pharmacists' education, knowledge, and experience preparing them to discharge their corresponding responsibility to properly handle controlled substances prescriptions with care, and pharmacists' duties and standard of care for dispensing prescriptions that may interact with other patient

medications. As such, NABP focuses on ensuring that pharmacies and pharmacists provide safe medication and patient services for American families.

- 26. NABP's work also includes warning consumers about websites that violate U.S. law regarding the manufacture, sale, and dispensing of foreign drugs. For example, NABP works closely with Song for Charlie, a nonprofit charity, to raise public awareness on the prevalence and dangers of fake pills sold online.
- 27. NABP combines diverse skills and backgrounds, which helps NABP create innovative programs that meet the public health protection needs of today—with an eye on the future.
- 28. In Washington, D.C., NABP's member, the District of Columbia Board of Pharmacy, regulates the practice of pharmacy and the practice of pharmaceutical detailing in the District of Columbia. Consistent with NABP's mission, the District of Columbia Board of Pharmacy promotes pharmacy and drug law compliance. The Board, consisting of seven DC residents—five licensed pharmacists and two consumers—evaluates applicants' qualifications; recommends standards and procedures; issues licenses; and receives and reviews complaints.

#### **The FDCA and Pharmacy in the United States**

- 29. The United States has a "closed system" pharmaceutical regulatory regime which keeps drugs under the oversight of the FDA. Under that system and prior to dispensing, drugs in the United States are continuously in the custody of a registered manufacturer, an authorized distributor, or a licensed healthcare provider. The importation of prescription drugs outside of this "closed system" is, for purposes of these counterclaims and in all circumstances relevant to PCC's facilitation business, unlawful.
- 30. In 2013, Congress introduced the Drug Supply Chain Security Act, which creates even more rigorous systems, with the goal of quickly removing dangerous or potentially dangerous

drugs from the legitimate drug supply chain. This tracking system is expected to be fully implemented by 2023; the FDA is currently implementing the system via pilot programs.

- 31. The FDA has, contrary to PCC's commercial representations, repeatedly "expressed the view that virtually all importation of drugs into the United States by individual consumers violates the FDCA. These drugs may not be approved and manufactured in accordance with the FDCA, they may not be appropriately labelled, or they may be dispensed without a valid prescription." Each of these would be a violation of the FDCA. In all or virtually all cases relevant here, personally imported drugs are from outside of the closed system. There is no continuous chain of regulatory oversight by the FDA of their manufacturing, transportation, and storage because these drugs are not made and kept continuously in the custody of registered manufacturers, authorized distributors, and licensed healthcare providers.
- 32. PCC goes out of its way to obscure the difference between drugs manufactured abroad at FDA-regulated facilities (which may be overseen by other regulators in addition to the FDA) and drugs manufactured abroad in general. The critical distinction is not where drugs are manufactured, but under what regulatory oversight they are manufactured. An FDA-approved drug manufactured under FDA's regulatory scrutiny in an FDA-approved factory in India or Israel that comes into the U.S. via an FDA-approved supply chain is an FDA-approved drug. It is subject—from manufacturing to dispensing—to oversight by U.S. regulators as part of a closed system. A non-FDA-approved drug may be made in those same countries—even in the same factories—but it is not the equivalent of an FDA-approved drug. It is not subject to the same oversight; it may be packaged for different uses; it may have different active or inactive ingredients; it may dissolve at a different rate; it may be stored differently.

- 33. A foreign-manufactured FDA-approved drug is not equivalent to a non-FDA approved drug purchased online through a pharmacy intermediary from a PCC affiliate that will not tell consumers its real name or disclose its licensing information. It is misleading to suggest otherwise.
- 34. Contrary to PCC's and its affiliated "verified" drug suppliers' representations to the consuming public that the purchase of foreign drugs from websites linked on PCC's platform are safe and identical to drugs legally dispensed in the United States, the FDA warns that, "without regulation of repackaging, storage conditions, and many other factors, drugs delivered to the American public from foreign countries may be very different from FDA approved drugs with respect to formulation, potency, quality, and labeling." *See In re Canadian Import Antitrust Litigation*, 470 F.3d 785, 789 (8th Cir. 2006).
- 35. Individuals have faced civil and criminal liability for aiding and abetting violations of the FDCA, as well as conspiracy to violate the FDCA. *See, e.g.* 21 U.S.C. § 331 (listing prohibited acts under the FDCA and prohibiting the "causing" of acts in addition to the acts themselves); 21 U.S.C. § 333 (listing penalties for violation of the FDCA); *United States v. Dotterweich*, 320 U.S. 277, 284 (1943) (noting that misdemeanor violations of the FDCA are strict liability offenses); 18 U.S.C. § 545 (prohibiting importation of goods "contrary to law"); 18 U.S.C. § 371 (prohibiting conspiracy "to commit any offense against the United States, or to defraud the United States, or any agency thereof. . . ."); 18 U.S.C. § 2 (providing that whoever "aids, abets, counsels, commands, induces, or procures . . . commission" of "an offense against the United States" is "punishable as a principal").
- 36. Unlawful importation can also form the basis for a mail or wire fraud conviction, or conspiracy to violate the mail or wire fraud laws. *See* 85 C.F.R. 66568-66569 (debarment order

against Keith Komar following his conviction for engaging in a conspiracy to "fraudulently import . . . misbranded bicalutamide and isotretinoin," and noting that Mr. Komar intended to sell the drugs on his website by way of false statements, including that the imported drugs were "high quality, safe, and approved medication meeting or exceeding the U.S. FDA standard").

- The Secretary of Health and Human Services is permitted to allow importation from Canada—but not any other country—but *only* after the Secretary makes a certification to Congress that such importation will "pose no additional risk to the public's health and safety" and that it will "result in a significant reduction in cost of covered products to the American consumer." *See* 21 U.S.C. § 384(1). The Secretary has *never* made such a certification with respect to personal importation and thus it remains prohibited.
- 38. Although HHS recently made certain certifications potentially allowing states and government entities to import from Canada, and no other country, if approved by the FDA, HHS has expressly declined to certify that the type of personal importation facilitated by PCC and its affiliates will "pose no additional risk to the public's health and safety" and that such personal importation will "result in a significant reduction in cost of covered products to the American consumer." *See* 21 U.S.C. § 384 (requiring certification from the Secretary of Health and Human Services regarding safety and cost before allowing limited importation); 21 C.F.R § 251.1-21 (allowing importation from Canada of drugs that meet specific criteria overseen by certain delineated government sponsors, *not allowing personal importation from Canada or any other country*, regulating pharmacists and pharmacies that are part of any program under the rules, and requiring those pharmacies to be "State-licensed," *i.e.* not foreign).
- 39. In fact, a recent federal rulemaking expressly warned that "medications purchased online and imported through international mail, express couriers, and other means pose significant

challenges for FDA and its ability to adequately safeguard the quality and safety of drugs taken by U.S. consumers." 84 Fed. Reg. 70796, 70800 (Dec. 23, 2019).

- 40. The type of personal importation at issue in this federal rulemaking is the exact type of personal importation that PCC encourages and facilitates through its business model and the exact type of personal importation that PCC and its affiliates falsely and misleadingly advertise to consumers as safe, trustworthy, and lawful. It is none of these things as a matter of fact and law.
- 41. PCC knows that the rule did not allow for personal importation because its cofounder and president Gabriel Levitt submitted a comment to the federal rulemaking on behalf of PharmacyChecker and Prescription Justice, arguing that the FDA *should* implement 21 U.S.C. § 384(j) and expressly referencing the FDA's statement that it is "not proposing to implement the personal importation provisions" in § 384(j). The comment also acknowledged the problem of "rogue Pharmacies that pretend to be Canadian," and stated that organizations like the Canadian International Pharmacy Association ("CIPA") and PCC accredit the safest "international pharmacies." In other words, it distinguished international pharmacy accreditation from other pharmacy accreditation. It also protested the FDA's reference to Canada Drugs Ltd. as an example of a rogue online pharmacy. *See* Comment from PharmacyChecker and Prescription Justice, Comments on Proposed Rule "Importation of Prescription Drugs," Doc. No. FDA-2019-N-5711, Comment No. FDA-2019-N-5711-1239 (Mar. 10, 2020).
- 42. The FDA has issued public safety warnings about the exact type of entities that PCC profits from, advertises for, and directly links to, which "purport to be from Canada or sell drugs approved in Canada," noting that "in many instances [imported drugs] are not actually from Canada and not approved by [the Canadian FDA analogue] . . . . A 2005 FDA analysis of drugs imported through international mail facilities revealed that while nearly half of imported drugs

claimed to be Canadian or from Canadian pharmacies, 85 percent of those drugs originated elsewhere and were fraudulently represented as Canadian." 84 Fed. Reg. 70796, 70800 (Dec. 23, 2019).

- 43. In a 2015 Indictment of CanadaDrugs.com and its executives—then a PharmacyChecker.com verified pharmacy<sup>2</sup>—the United States Department of Justice went into detail about the requirements of the FDCA, including manufacturing requirements and the requirement that drugs be labelled in compliance with the Act, stating as follows:
  - a. The Food and Drug Administration ("FDA") was the agency of the United States responsible for regulating the manufacture, labeling, and distribution of drugs in the United States. Among other things, the FDA was responsible for enforcing the provisions of the Federal Food, Drug, and. Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), including regulating the distribution of prescription drugs.
  - b. Before a new drug could be introduced into interstate commerce, it must have been the subject of an approved application filed with the FDA. *See* 21 U.S.C. §§ 331(d), 355(a). FDA approval was not only for the molecular entity itself (i.e. the active ingredient) but also included the manufacturing process and labeling. *See* 21 C.F.R. § 314.50(i).
  - c. FDA is responsible for regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce, including the distribution of

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<sup>&</sup>lt;sup>2</sup> The internet archive includes a capture of PCC's "online pharmacy ratings page" from July 10, 2015—one week before the CanadaDrugs.com indictment was filed listing CanadaDrugs.com as an "approved" pharmacy and noting that it dispenses from Barbados, Canada, New Zealand, and the United Kingdom. CanadaDrugs.com is no longer listed as an approved pharmacy, and none of PCC's current approved pharmacies claim to dispense from Barbados. The indictment of Canadadrugs.com is discussed in more detail below because at least one of PCC's approved pharmacies requires that customers give it permission to share their personal health information with CanadaDrugs.com despite no warning from PCC of that pharmacy's link to the convicted company.

prescription drugs. FDA's responsibilities include enforcing the FDCA's requirements that drugs bear labels and labeling that enable health care providers and consumers to use them in a safe manner and that the drugs are listed by and manufactured in facilities registered with the Secretary of the United States Department of Health and Human Services. 21 U.S.C. §§ 352(f), 352(o), 360(c), and 360(i).

- d. The FDCA establishes that a drug is deemed to be "misbranded" if it does not meet certain requirements of the statute, including if its labeling fails to bear adequate directions for use, 21 U.S.C. § 352(f), if information required to appear on the label is not in the English language (unless distributed solely in Puerto Rico or certain U.S. territories), 21 U.S.C. § 352(c), 21 C.F.R. § 201.15(c)(1), or if a drug came from a foreign drug establishment and the drug was not annually listed with the FDA by that establishment as one of the drugs which was being manufactured for commercial distribution in the United States, 21 U.S.C. §§ 352(o), 360(j). In the case of a prescription drug, a drug is also misbranded if its label fails to bear the symbol "Rx only." 21 U.S.C. § 353(b)(4)(A); 21 C.F.R. § 201.100(b)(1).
- e. The FDCA prohibits the introduction, or causing the introduction, of misbranded or unapproved new drugs into interstate commerce. 21 U.S.C. §§ 331(a), (d).
- 44. As discussed below, CanadaDrugs.com eventually pleaded guilty to selling misbranded and counterfeit drugs in violation of the FDCA.
- 45. Pharmacies in the United States are also regulated by state boards of pharmacy and required to follow state<sup>3</sup> pharmacy laws where they are located as well as pharmacy laws where

<sup>&</sup>lt;sup>3</sup> State in this context includes the District of Columbia and U.S. territories.

their patients are located. In almost every state, this means that pharmacies must be licensed in their home state and each additional state to which they dispense medication. There are only limited exceptions to the generally required non-resident state licensure.

- 46. Online pharmacies that dispense in the United States must comply with the pharmacy rules in the states to which they dispense medication.
- 47. While there are broad similarities in many state regulatory regimes, different states can and do take different approaches to ensure patient health, safety, and welfare.
- 48. Licensed pharmacists help patients understand and manage their medication therapies, coordinate care, save patients money based on their unique insurance coverage and medication needs, detect prescribing errors, and counsel patients on how to identify and handle adverse reactions.
- 49. Prescribing rules and standards can and do vary by jurisdiction, and upon information and belief pharmacists licensed in a given jurisdiction are responsible for knowing and following applicable standards.
- 50. State pharmacy regulators are empowered to discipline pharmacies and pharmacists that do not comply with pharmacy practice laws and rules; they also publicize when disciplinary or legal action has been taken against a pharmacy.
- 51. State law also regulates which entities may be called a pharmacy. In many states, including in Washington, D.C., an entity cannot hold itself out to be a pharmacy unless it is a licensed pharmacy. *See, e.g.*, D.C. Mun. Regs. tit. 22, § 1900 ("It shall be unlawful for an establishment or institution, or any part thereof, that does not provide services of the practice of pharmacy, as defined within, to use or have upon it, or displayed within it, or affixed to, or used in connection with it, a sign bearing the word or words "pharmacy," or "apothecary," "drug store,"

"druggist," or any word or words of similar or like import...."); S.C. Code Ann. § 40-43-86(R)(1) ("It is unlawful for any person, except a pharmacist licensed under this chapter and pursuant to the regulations of the board of pharmacy to: (a) take, use, or exhibit the title 'pharmacist,' 'druggist,' 'pharmacy'....").

#### I. PCC's Commercial Mission

52. PCC's entire business model exists to directly connect U.S. consumers, including those in Washington D.C., to PCC's "verified" pharmacy sites (the vast majority of them foreign) selling foreign pharmaceuticals that these consumers cannot lawfully buy. PCC's blog, for example, extols the virtues of personal importation and links consumers to PharmacyChecker.com for the purpose of linking to PCC's affiliated foreign drug suppliers to unlawfully purchase drugs that the FDA has deemed unsafe. PCC's accreditation business is devoted to this same singular goal of facilitating consumer purchases of foreign pharmaceuticals—PCC accredits these foreign drug suppliers for the sole purpose of featuring them on PCC's site, advertising these affiliated entities' products and prices, and linking directly to the foreign drug suppliers so consumers can consummate their unlawful and unsafe transactions. PCC's price comparison tool is unmistakably designed to advertise what PCC describes as purportedly the lowest possible pricing, again for the direct and sole purpose of facilitating unlawful drug importation. And PCC's drug discount card, which is a rebranded card available to consumers elsewhere, upon information and belief, is used to draw in consumers for the purpose of directing them to the PCC-verified "pharmacies" referenced above that work in concert with PCC to facilitate unlawful personal importation. In other words, all roads of PCC's business lead consumers to PCC's price comparison tool and/or PCC's affiliated, foreign drug supply sites for the express purposes of fostering and profiteering from unlawful drug importation.

- 53. PCC receives the vast majority of its revenue (from click-fees when consumers use its site to access the unlawful pharmacies that it "accredits". PCC data establishes that, during the relevant time period, American consumers clicked through from PCC's website to its verified pharmacies over times. Over of these clicks originated from consumers in Washington, D.C. Approximately times, these clicks connected D.C. consumers to PCC's foreign verified pharmacies (and not U.S.-based pharmacies).
- 54. According to just one of PCC's then-accredited foreign pharmacies' records (Affordable Rx), at least four consumers located in Washington, D.C., were referred by PCC or clicked through from PCC's website to that PCC-verified foreign pharmacy and purchased prescription drugs shipped from abroad—some more than once. Upon information and belief, that referral occurred when D.C. consumers visited or checked PharmacyChecker.com or interacted with the PharmacyChecker seal. Upon information and belief, average e-commerce conversion rates are around 2.5-3%, meaning on average, clicks result in a transaction 2.5-3% of the time. Upon information and belief, additional D.C. consumers completed purchases from one or more of PCC's verified pharmacies following a click from PCC's website.
- 55. PCC is also paid monthly by its so-called "verified" pharmacies to provide its certification so that these unlawful pharmacies can signal legitimacy to U.S. consumers and so those U.S. consumers will unlawfully purchase pharmaceuticals. For example, Affordable Rx Meds's front page prominently features its accreditation by PCC. While it holds itself out as a U.S. "pharmacy" based in Miami, Florida, it relies solely on foreign pharmacies to fulfill orders, dispensing from their "licensed and independently verified pharmacy partner from India and Turkey shipped from an international fulfillment center that is approved by the regulatory bodies from their country."

#### Welcome to Affordable Rx Meds, Miami, Florida, USA

#### Affordable Prices

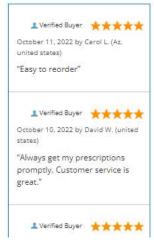
Affordable medications come with a price --- A Valid Affordable Rx Meds is a leading online pharmacy focused prices can be as much as 40% to 80% less, than at your should go without needed medications due to inflated local pharmacy. You can quickly and easily buy medicine pricing or budget constraints. We are dedicated to provide online. We also provide the facility of ordering prescription you the high-quality prescription medication you need. while buying prescription medicine online; please do not price with a smile. hesitate to contact our toll-free customer support center.

#### Customer Service

Prescription. Give us a valid prescription and we will on providing safe and affordable prescription drugs to provide your meds at a greatly discounted price. The thousands of customers. We strongly feel that no one medicines via telephone, fax, or email. For any assistance, You can now buy medicine online USA at an affordable

### echeck Zelle





#### Quality and reliability

Quality and reliability is provided to you by delivering prescriptions in tamper proof packaging and where applicable in the manufacturer's original packaging while saving you money.All orders placed on our website Affordable Rx Meds are dispensed from our licensed and independently verified pharmacy partner from India and Turkey shipped from an International fulfillment center that is approved by the regulatory bodies from their country

#### AffordableRxMeds Customers Benefits

- · Medication sourced from fully licensed, PharmacyChecker approved pharmacles
- . Lowest price guarantee, we will meet or beat any PharmacyChecker approved pharmacy
- \$15 shipping on all orders to the United States
- · A secure website with confidential ordering
- · High quality medications dispensed by licensed oharmacists
- Customer support and order line available 7 days a

56. PCC also collects fees for participation in its "Pharmacy & Drug Price Listing Program," through which PCC links to its verified pharmacies' home pages and/or drug-specific pages on the PCC website and/or drug price search comparison results pages allowing consumers to access the home page and/or drug-specific page on the affiliates' sites with a single click. Notably, PCC

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57. PCC claims that it was created "to meet a critical need," as "pharmacies and Canada began selling prescription drugs to Americans over the internet that they could not afford," and that they exist to "provide consumers, mostly in America, with information that helps them find the most affordable and safe prescription drugs from online pharmacies, including those located in Canada and other countries." Indeed, PCC proudly touts that its "forte" is "international online pharmacies' prices."

58. PCC also started a blog to "fight back" against efforts to prevent Americans "from obtaining safe and more affordable prescription drugs from Canada and other countries." Contrary to PCC's representations, that its blog is somehow distinct from its PharmacyChecker.com site and is for consumer education purposes only, PCC's blog in its "History of PharmacyChecker Blog" page, specifically reiterates the message above about PharmacyChecker.com's claimed purpose to connect primarily American consumers with foreign pharmacies for personal importation and ties it to the creation of the blog. Further highlighting the economic motivation and clear commercial purpose of PCC's blog, it contains the same search box that exists on PharmacyChecker.com's price comparison tool that allows consumers to search for and purchase foreign drugs from PCC's "accredited" foreign pharmacies:



59. PCC's blog posts also often redirect consumers through included hyperlinks to PharmacyChecker.com articles that provide more information on a given topic. For example, one blog post includes a hyperlink that redirects consumers to a PCC article that headlines "Brand Drugs Are 90% Cheaper and Available to Order From International Pharmacies," then explicitly compares domestic and international drug prices and assures consumers that "[PCC-] Accredited online pharmacies are verified and monitored for marketing claims, privacy policies, data security, pharmacist consultation availability, and other high standards of online pharmacy practice. PharmacyChecker conducts onsite inspections of pharmacies in several countries including India,

Mauritius, Singapore, and Turkey." It goes on to boast that PCC is the only "independent company that monitors and verifies the credentials of international online pharmacies and publishes price comparisons between those pharmacies and local U.S. pharmacies."

- 60. The PharmacyChecker.com website also links to and maintains a dedicated page to the PharmacyChecker Blog, where it keeps an up-to-date list of PCC's blog entries with the most recent entries at the top.<sup>4</sup> PCC's suggestion that its blog is non-commercial in nature is fiction.
- 61. On the front page of its website, PCC asks consumers "How Much can you save with an online pharmacy?" But rather than connect consumers with lawful online pharmacies, it shows them "Savings on Popular Medications using Canadian and International Online Pharmacies."
- 62. After telling consumers that "it's easy to compare drug prices among trusted international pharmacies," PCC then tells consumers that "Comparing drug costs on PharmacyChecker.com helps you and your family save the most money," implying that consumers can and should save money by purchasing from their "accredited" pharmacies.
- 63. PCC affirmatively tells consumers that the prices it provides come from pharmacies "verified as safe" that are "continuously monitored." It also claims that the drugs they sell are "lawfully manufactured," "genuine," and "regulated."
  - 64. All of these claims are misleading.
- 65. While PCC claims to be connecting consumers with foreign pharmacies in the name of "affordability," it has sidestepped the American system for making drugs affordable—genericization. The front page of PCC's website highlights a number of brand-name medications

21

<sup>&</sup>lt;sup>4</sup> PCC has since abandoned its blog efforts, telling consumers "PharmacyChecker Blog has discontinued publishing new posts. For more policy and politics surrounding drug importation, drug prices, online pharmacies and safety, go to PolicyPrescription.com." PCC still maintains the PharmacyChecker Blog page with all its historical content and the dedicated page on PharmacyChecker.com linking to the blog.

including Nexium, and Zetia, and notes the "international pharmacy savings for these drugs. Both of these drugs have been genericized however, and upon information and belief generic drugs are nearly always substantially cheaper than brand name drugs. In fact, a 2004 FDA study found that generic drugs are often cheaper than both Canadian brand-name drugs and Canadian-generic drugs.<sup>5</sup>

- 66. Upon information and belief, more than 90% of prescription drugs dispensed in the United States are generic drugs.
- 67. One of the benefits of connecting consumers with pharmacists that are actually licensed to dispense drugs to the patients that they are selling to is that those pharmacists can work with their patients and the patients' medical provider to determine when substituting a generic drug may be appropriate—saving the patient a substantial amount of money and not subjecting the patient to legal jeopardy including, but not limited to, the risk of confiscation of their drug shipment or the risk of law-enforcement contact.

# II. Pharmacy-Checker's False and Misleading Claims About its "Accredited" Pharmacies and the Legality, Safety, and Other Material Attributes of the Drugs they Sell to Unwitting U.S. Consumers

- 68. PCC's website makes a variety of different claims that mislead consumers, including those in Washington, D.C. These include:
  - a. Statements that mislead consumers about the legal risk of buying foreign pharmaceuticals and/or the relationship between non-FDA-regulated foreign pharmaceuticals and FDA-regulated pharmaceuticals;
  - b. Statements and design choices hiding that the pharmacy websites PCC sends consumers to are not pharmacies at all;

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<sup>&</sup>lt;sup>5</sup> https://www.fda.gov/drugs/resources-you-drugs/study-us-generic-drugs-cost-less-canadian-drugs.

- c. Statements that mislead consumers into believing that they are receiving the "lowest price" "worldwide" by buying through an anonymous foreign pharmacy rather than, for example, buying the generic version of a branded drug from their local pharmacy or working with their insurance company and/or a drug manufacturer to find the lowest domestic price on a branded drug;
- d. Statements that mislead consumers about the origin of the drugs that they are buying;
- e. Statements that mislead consumers about the safety and trustworthiness of PCC's accredited pharmacies.

## A. Statements that Mislead Consumers About the Legality of Personal Importation and the Relationship Between Foreign Pharmaceuticals and FDA-Approved Pharmaceuticals

- 69. PCC goes out of its way to hide information on legality and to provide misleading information on the legality of purchasing drugs from foreign pharmacies. It does this as part of its unlawful business model where it makes money "verifying" and facilitating purchases from foreign pharmacies that violate U.S. law so that they can launder their reputation for U.S. consumers, and it makes money when U.S. consumers use links on its website to access those pharmacies.
- 70. PCC hides information about legality on its website, providing misleading information about risk (affirmatively telling consumers that they face no risk of arrest, and not mentioning the risk of confiscation), conflating more-regulated Canadian pharmacies with loosely regulated pharmacies in Caribbean free trade areas, implying that foreign pharmacies and pharmacists licensed in their home jurisdictions are as legitimate and trustworthy as, or otherwise comparable to, domestic pharmacies and pharmacists licensed in the U.S., and implying that foreign pharmaceuticals are as safe as—and even identical to—FDA-approved pharmaceuticals.

- 71. PCC tells consumers that they are dealing with "verified" pharmacies that they can trust, while sending unwitting consumers to "Pharmacy Intermediaries" that dispense through third party foreign pharmacies and dispensaries which refuse to provide their names or license numbers to consumers. It also "verifies" a number of pharmacies that go to great pains to make it appear to consumers that they are dispensing from Canada, providing only small-text disclaimers that they will likely ship drugs not from Canada but from other jurisdictions, including the Mauritius Free Trade Zone, India, or Turkey. PCC misleads consumers to think that they are dealing directly with a "trusted" *Canadian pharmacy*, when in reality, he or she is dealing with an undisclosed and unregulated "intermediary" that will ship unregulated drugs from an anonymous company maintaining a warehouse somewhere in, for example, Turkey.
- 72. PCC misleads consumers into believing that the drugs that they are receiving are the same as or equivalent to FDA-regulated drugs. This is false. Even a brand-name drug sold under the same name in multiple jurisdictions may differ; the drugs may use different inactive ingredients, different release mechanisms, or be manufactured in different facilities. The drug will almost certainly be differently packaged with different instructions for patients, and it may not have been stored, manufactured, and/or transported in accordance with FDA-regulations. PCC goes to great pains to mislead consumers about the very real differences between FDA-regulated drugs and non-FDA-regulated foreign drugs. These differences can be dangerous.
- 73. In a November 18, 2020 post and email that PCC disseminated to consumers, PCC misleadingly represented that personal importation is lawful: "If you need your medication quickly, then you should consult your local pharmacy *and then you can purchase the rest of your prescription internationally.*" PCC's post then provides a link to PCC's "Verified Safe Pharmacies," where consumers can easily consummate their drug purchases.

74. PCC is more explicit elsewhere in its commercial speech regarding the purported legality of purchasing drugs through PCC's website, explicitly representing that, despite some alleged confusion regarding whether personal importation is lawful in the U.S., consumers "can do it!" In a March 5, 2021 post, PCC falsely and misleadingly represented to consumers regarding the legality of personal importation as follows:



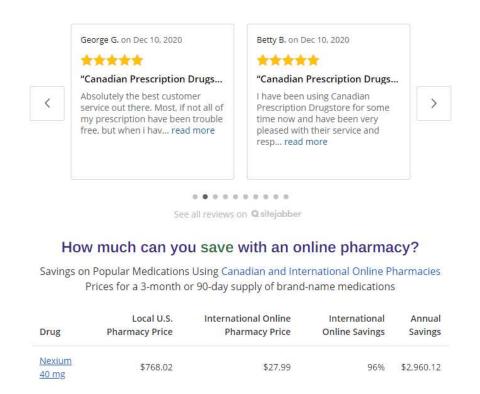
- 75. This same post goes on to represent that, "unlike with wholesale importation, federal law ranges from forgiving to expressly permitting otherwise prohibited importation for personal use." These representations are false and misleading and designed to and do encourage consumers to then break the law by purchasing foreign pharmaceuticals via PCC's website and the links PCC provides to its affiliates foreign drug suppliers.
- 76. PCC even admitted—in a comment on the FDA's 2020 state-sponsored importation rule—that the FDA has not used authority from Congress to allow personal importation, that the authority, if exercised, would only allow imports from Canada if it were implemented, and that there is danger associated with the use of foreign pharmacies that pretend to be Canadian but dispense from elsewhere.

77. The front page of PCC's website also tells consumers it provides "Prescription Savings You Can Trust" and includes a list of popular searches and the statement "Verified International & Canadian online pharmacy options. Free U.S. pharmacy coupons. Compare drug prices and save up to 90%." PCC includes a "featured in" banner which represents that The New York Times, Yahoo Finance, Healthline USA Today, and the AARP, among others all approve of PCC's business model and recommend that consumers use PCC's platforms to purchase unlawful foreign drugs. A screenshot is below:



- 78. At a minimum, PCC's speech strongly implies that consumers can "trust" PCC's "verified pharmacy" options, that they can save on drugs through these pharmacies, and that they have the support of all of these recognizable organizations. None of these things are true.
- 79. To imply that the purchase and importation of foreign drugs is both commonplace and legal, PCC posted glowing "consumer" reviews of PCC verified drug sellers that claim to be Canadian (as described later, many of these sellers are not actually "pharmacies" and dispense from countries other than Canada) as recently as May 2021 on its main page. Again, implying that personal importation is a legal option, PCC then asks "How Much can you Save with an Online

Pharmacy" and shows consumers "Savings on Popular Medications using Canadian and International Online Pharmacies."



- 80. PCC features consumer reviews on a dedicated "Patient Reviews" page, telling PCC site visitors that "Patients and Health Professionals Recommend PharmacyChecker Savings & Safety Information."
- 81. The front page of PCC's website also includes an auto-playing slide show, which includes statements that further mislead consumers regarding the legality of personal importation. In non-prominent white text against a light grey background, PCC represents to consumers: "The U.S. government has not legalized personal importation, but no one has ever been prosecuted for importing small quantities of medication for their own use. Ever."



- 82. Of course, the implication that the U.S. government has "not legalized" personal importation and that nobody has "ever been prosecuted" strongly suggests to consumers that the U.S. government has not addressed the issue at all and thus importation is lawful. And PCC's representation that importation of "small quantities"—an intentionally ambiguous term—is permissible is also, at best, misleading. Contrary to PCC's statements and misrepresentations, the U.S. government has affirmatively criminalized the precise personal drug importation at issue in this lawsuit.
- 83. This is the only mention of legality on the front page of PCC's website, it is displayed for only a few seconds and then disappears, and is designed to misleadingly give consumers the impression that they can and indeed should buy non-FDA-approved drugs from the foreign drug sellers that PCC hosts, advertises, and links to on its platform.

- 84. Indeed, the FDA makes clear that it is "illegal for individuals to import drugs into the United States for personal use." In other words, PCC asks "is it legal," and answers "nobody has ever been prosecuted." The two are not the same. And elsewhere, PCC unambiguously reassures U.S. consumers that "You can do it!"
- 85. In addition, PCC's "Price Comparison" page misleadingly equates foreign drugs with FDA-approved drugs. For example, it states that "some but not all drugs sold in Canada are the exact same. People tend to assume that drugs sold in the United States are made in the United States and drugs sold in Canada are made in Canada, which is often not the case. Medications sold in the U.S. and Canada are manufactured in countries located throughout the world."
- 86. PCC's statements obfuscate the relevant issue—the issue is not *where* drugs are manufactured, but *under what regulatory oversight* they are manufactured. An FDA-approved drug manufactured under FDA's regulatory scrutiny in an FDA-regulated facility in India or Israel that comes into the U.S. via an FDA-approved supply chain and that is dispensed by a licensed healthcare provider is an FDA-approved drug. It is subject—from manufacturing to dispensing—to oversight by U.S. regulators as part of a closed system. A non-FDA-approved drug may be made in those same countries—even in the same factories—but it is not the equivalent of an FDA-approved drug. It is not subject to the same oversight; it may be packaged for different uses; it may have different active or inactive ingredients; it may dissolve at a different rate; it may be stored differently.

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<sup>&</sup>lt;sup>6</sup> https://www.fda.gov/about-fda/fda-basics/it-legal-me-personally-import-drugs. The FDA has a "policy" of "not object[ing]" to some imports—for example, serious diseases with no approved U.S. treatment if the individual provides verification to the FDA. Drugs for which there is an equivalent available in the U.S. do not fit within this policy. There is no exception to the FDCA for cost. The policy also does not make the importation "legal" in any sense.

- 87. A foreign-manufactured FDA-approved drug is not equivalent to a non-FDA approved drug purchased online through a pharmacy intermediary from a PCC affiliate that will not tell consumers its real name or disclose its licensing information. It is misleading to suggest otherwise. The law is clear: the types of drug purchases that PCC facilitates are unlawful and PCC's statements to the contrary are false, misleading, and have dangerous implications for patient safety.
- 88. PCC's false and misleading representations regarding the legality and safety associated with personal importation of the cancer treatment drug Ibrance take on a particularly predatory character. In a January 28, 2021 post, PCC represents that consumers face two choices in purchasing this drug: "The cancer treatment drug Ibrance, for example, is over \$27,000 for a 90-day supply in the U.S. vs. \$13,000 in Canada." PCC goes on to state that "Canadian pharmacies and pharmacies in other countries could offer a practical lifeline for Americans" and that consumers should "shop at [drug suppliers] accredited through the PharmacyChecker Verification Program" to buy Ibrance. PCC provides a link to these foreign pharmacies again misrepresenting that U.S. consumers can legally and safely purchase Ibrance and should do so to save over 50% or, in this case, \$14,000. PCC does not mention lawful options including, but not limited to, payment plans, manufacturer coupons, or options to work through insurers or government programs like Medicare, Medicaid, or the VA to lawfully achieve savings. While PCC's savings advice sounds very appealing to U.S. consumers, it is also unlawful and the use of non-FDA-regulated drugs can jeopardize patient safety.

#### B. PCC Hides that the "Pharmacy" Websites It Links to Are Not Pharmacies at all

89. PCC's website contains an "Online Pharmacies" page that repeatedly uses the word pharmacy; referring to "Accredited Canadian and International Online Pharmacies," it tells consumers that it is "Your trusted list of the best online pharmacies that sell safe, affordable

medication online." It also calls those pharmacies "reputable, accredited, and monitored," and notes that "Accredited Pharmacies have locations in Canada, Australia, India, Mauritius, New Zealand, Turkey, the UK, and the United States."

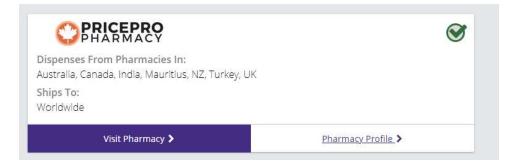
90. PCC's "online pharmacies" page and its list of affiliated purported "pharmacies" is false and misleading. Once a consumer clicks the link they are greeted in large, bolded font with the words: "Accredited Canadian and International Online Pharmacies." Each such "pharmacy" also has a link that says "Visit Pharmacy." A May 2021 screenshot of the page and the first displayed "pharmacy" is below:

### Accredited Canadian and International Online Pharmacies

Your trusted list of the best online pharmacies that sell safe, affordable medication online

PharmacyChecker online pharmacy verifications and drug price comparisons are widely trusted and referenced in media sources, such as AARP Magazine, the Wall Street Journal, Yahoo Finance, the New York Times, Kaiser Health News, and many others.

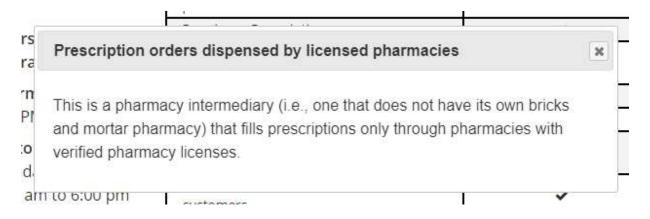
Review our list of reputable online pharmacy websites that are accredited and monitored through the PharmacyChecker Verification Program. Accredited pharmacies have locations in Canada, Australia, India, Mauritius, New Zealand, Turkey, the UK, and the United States. Most pharmacies ship worldwide.



91. There is a second link, however, to visit the "Pharmacy Profile," on the current PCC website-iteration styled as "Review Online Pharmacy." Once you get to the second page, there is a table for each "International Online Pharmacy" showing the "PharmacyChecker verification status." The table for PriceProPharmacy looks like the following:

PharmacyChecker Verification Status	Verified
Prescription orders dispensed by licensed pharmacies	~
Requires a Prescription	~
International sales of controlled drugs to the U.S. prohibited	~
Meets website security requirements	~
Publishes customer privacy policy on website	~
Publishes contact information on website for customer service	~
Pharmacist consultation offered to customers	~
Quantities marketed on website restricted to a maximum of 3 months' supply at a time	~
Disclosure of pharmacy location to consumer prior to purchase	~
Marketing claims are truthful and not misleading	~

92. However, there is a hidden link on the "Prescription Orders dispensed by licensed pharmacies" box, which when clicked reveals the following disclaimer:



93. In other words, these purported "verified" "pharmacies" are not pharmacies at all. For example, each and every "pharmacy" currently on the PCC Accredited Online Pharmacies page is a "pharmacy intermediary." This information is hidden by default to consumers. They are online middlemen for other "pharmacies." At the bottom of the page there is a list of countries

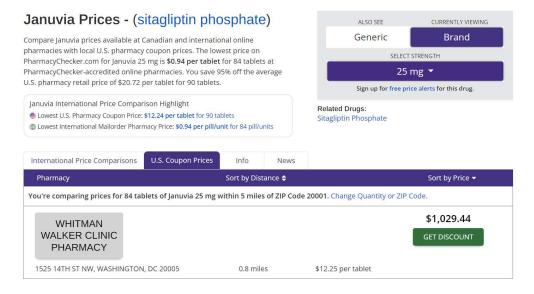
with pharmacies that these "pharmacy intermediaries" use. For nearly all of the "verified dispensing pharmacies" used by the pharmacy intermediaries, PCC has a statement saying that the name and license number of the dispensing pharmacy are not being published by PCC at the request of the pharmacy intermediary.

94. In other words, PCC tells consumers that it is sending them to "verified pharmacies," but instead it is sending them to intermediaries, and the true names and license numbers of the "pharmacies" they are purchasing from are hidden.

#### C. Statements that Mislead Consumers on Price

- 95. In addition to being riskier than FDA-regulated drugs, imported drugs are often more expensive than domestic drugs. Generic drugs—which make up the vast majority of prescription drugs dispensed in the United States—are often cheaper in the United States than anywhere else in the world. FDA-regulated generics are subject to the same oversight as FDA-regulated brand name drugs.
- 96. In fact, PCC has structured its business, including its blog and its PharmacyChecker.com site, to direct consumers *away* from low-priced, legal, domestic generic drugs and *toward* the more expensive branded drugs sold by the "verified" foreign "pharmacies" that pay PCC a fee to be listed on PCC's website.
- 97. State-regulated pharmacies are often required to take steps to save patients money. For example, a number of states require a pharmacist to dispense a less expensive generic version of a drug even if a prescription is written for a brand drug. In Washington, D.C., when pharmacists substitute a generic drug for the brand drug, they must dispense the least expensive product to patients. Under New York law, a patient cannot independently purchase brand drugs without prescriber pre-approval.

- 98. PCC's statements regarding consumers' ability to obtain the lowest possible prices from PCC's foreign affiliated drug suppliers are false and misleading, even with respect to some branded drugs.
- 99. For example, PCC represents to consumers that "the lowest price on PharmacyChecker.com for Januvia 25 mg is \$0.94 per tablet for 84 tablets at PharmacyChecker-accredited online pharmacies. You save 95% off the average U.S. pharmacy retail price of \$20.72 per tablet for 90 tablets." Despite PCC's representation that the "lowest price" for Januvia is thus \$78.96 from PCC's foreign affiliated drug supplier, many U.S. consumers, including those in Washington, D.C., can in fact lawfully purchase FDA approved Januvia prescriptions from safe, domestic pharmacies for as low as \$5.00 per prescription—or more than \$70 less than what PCC advertises as a consumer's "lowest" possible price.
- an actual customer purchase experience. When, for example, consumers from zip code 20001 search for the price of Januvia in the Washington, D.C. area, PCC affirmatively represents to consumers that "the lowest price with a U.S. Prescription Discount Coupon" at U.S. pharmacies is \$1,029.44 compared to \$78.96 from PCC's international, online drug suppliers.



101. In May 2021, when a consumer from zip code 10601 from White Plains, NY searched for the price of Januvia in their area, the PCC website even broadcasted a "SAVINGS ALERT" in red font alerting the consumer to the fact that "lower prices for Januvia 25 mg are available from accredited international online pharmacies."

The lowest price with a U.S. Prescription Discount Coupon in or near WHITE PLAINS, NY (ZIP Code 10601) is \$16.27 per tablet for 84 TABLETs at SOLEO HEALTH, 18% off the average retail price of \$19.98 per tablet for 84 TABLETs. Purchasing higher quantities usually means lower prices.

**SAVINGS ALERT:** Lower prices for Januvia 25 mg are available from accredited international online pharmacies, starting at **\$1.02** per pill or unit for a quantity of 84.

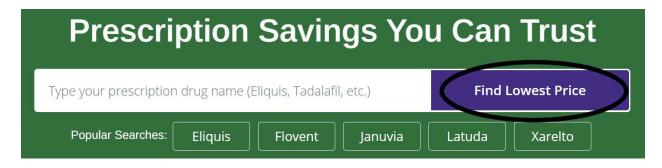
#### SEE LOWER PRICES

Pharmacy	Sort by Distance 💠	Sort by Distance 💠		
SOLEO HEALTH			\$1,366.80	
			GET DISCOUNT	
4 SKYLINE DR, HAWTHORNE, NY 10532	4.8 miles	\$16.27 per tablet		

- 102. PCC's representations, deliberately designed to steer consumers, including those in Washington, D.C., away from U.S. pharmacies and toward PCC and its affiliated foreign pharmacies, are false and misleading.
- 103. Upon information and belief, insured consumers with a manufacturer discount coupon at the time of this search in October 2022, could purchase Januvia for as little as \$5 from domestic pharmacies, not the "lowest" price of \$1,029.44 that PCC advertises. Thus, with a manufacturers' coupon, an insured U.S. patient could pay \$5 (upon information and belief, an insured patient could even pay \$0) for his or her Januvia prescription. But if he or she had done research on PCC, he or she might incorrectly believe his or her alternatives are paying thousands of dollars domestically, or hundreds of dollars through PCC and its affiliates for non-FDA regulated drugs that claim to be equivalent.
- 104. PCC's speech is designed to scare consumers away from cheaper, lawful pharmaceutical purchases from domestic pharmacies and toward purchasing illegally via

PharmacyChecker.com—as PCC tells consumers, "The lowest price on PharmacyChecker.com" is lower than the prices PCC displays for U.S. pharmacies.

- 105. PCC's false and misleading statements thus not only facilitate unlawful drug importation, they endanger patient health and may ultimately lead to American consumers, including those in Washington, D.C. and elsewhere, paying more than they have to for their prescriptions. PCC would have the Court believe that its consumers are making a rational decision to trade the safety of the American pharmaceutical regulatory system for savings; in fact, they may well get neither.
- 106. PCC tells consumers that it is helping them "find the lowest price," but it directs consumers in the first instance to its own accredited pharmacies; consumers must jump through additional hoops to search for often lower prices at domestic pharmacies, and even then, PCC limits its search to domestic pharmacies relatively close to the consumers' homes. Consumers must enter a zip code to search for prices at domestic pharmacies, avoiding much of the benefits of the safe, lawful, online pharmacy ecosystem that NABP has fostered in the U.S. A consumer can more easily order drugs from Mauritius via PCC than compare domestic and/or generic drug prices.
- 107. PCC tells consumers that it will objectively permit them to "find the lowest price," but then favors its own "verified" pharmacies:



# Compare Drug Prices in the U.S. & Abroad Before You Buy Enter drug name Find Lowest Price

108. PCC also tells consumers that it is helping them to "save the most money" and that foreign drugs "cost a lot less." For example, the page outlining its services states:

The cost of medication is different from country to country and pharmacy to pharmacy. To find the lowest drug prices, it's often essential to compare medication costs locally and internationally. Using PharmacyChecker.com, it's easy to compare drug prices among trusted international online pharmacies, including licensed Canadian pharmacies and local U.S pharmacies. Comparing drug costs on PharmacyChecker.com helps you and your family save the most money and avoid getting burned by rogue websites. (Emphasis added).

- 109. PCC also states that "Educated consumers know that the best prices on prescription drugs can be found on the Compare Prices pages of our site." Upon information and belief, this statement is simply untrue for most drugs purchased by most consumers.
- 110. The vast majority of drugs sold in the United States are generic drugs. A number of studies have shown that generic drugs, regulated by the FDA, are as cheap or cheaper than foreign generic drugs and even foreign branded drugs, even setting aside the additional financial and legal risk of purchasing non-FDA-regulated foreign drugs.
- 111. The PCC website shows consumers its "accredited" foreign pharmacies in the first instance. If consumers elect to try and navigate PCC's system to perform more complicated additional searching, they can see some generic prices at an incomplete list of pharmacies but only within a single zip code *if* PCC lists the drug at all. For a consumer to get the "best prices," he or she should be enabled to look at a broader slice of safe, lawful, online pharmacies than those PCC displays in his or her own zip code.

- 112. A consumer looking at PCC's website will also not be able to compare the best prices available at pharmacies through his or her health insurer, or affiliated pharmacies or pharmacy benefits managers, which can often offer a consumer significant savings even if he or she has not met a deductible. PCC does not even mention these common methods of saving money on safe, domestic drugs.
- 113. A consumer can also achieve savings by meeting a deductible faster or by paying from a Flexible Spending Account or Health Savings Account; purchases from foreign pharmacies, even PCC-accredited foreign pharmacies, will not help consumers achieve those savings. PCC ignores all of this, instead steering consumers to its own truncated subset of foreign drug suppliers.
- 114. PCC's blog also tells consumers that "the largest pharmacy savings on the Internet are from international online pharmacies which can offer you the lowest prices worldwide. These prices can be found on PharmacyChecker.com." These statements are at best misleading. PCC's business model depends on foreign pharmacies paying PCC for verification *and* for clicks (
- 115. As a result, PCC claims to be providing consumers with "the lowest prices worldwide," but in fact it is privileging the prices offered by its own "verified pharmacies," without being up front with consumers that this is what they are doing.
- 116. A consumer that could save money purchasing a generic at a safe, legal, domestic online pharmacy would never know it from PCC's website. Instead, they are nudged toward purchasing brands. These brands may be cheaper from foreign pharmacies than they are at domestic pharmacies (but often are not); they also are from outside the American regulatory system, and may in fact be materially different from the domestic brand. PCC deliberately makes all of this information, at best, opaque.

117. In other words, consumers importing drugs illegally through PCC's website sacrifice the safety of the FDA-regulated supply chain and the expertise and accountability of licensed and accredited pharmacists for savings that often do not even exist.

# D. Statements that Mislead Consumers About the Origin of the Drugs They are Buying

- 118. PCC "pharmacies" hide the fact that they dispense from countries other than Canada and hide the names of the countries they dispense from; many display the word Canada or "Canadian" prominently, as well as Canadian maple leaf iconography, and only disclose late in the customer experience and in non-prominent text that consumers could easily miss that they are receiving drugs from countries other than Canada, and drugs that are not regulated by Canadian authorities. Many of these pharmacies will not even ship to Canada.
- 119. These are not just misrepresentations by PCC's foreign affiliates. Rather, PCC warrants to consumers visiting PCC's platform that, as part of PCC's "accreditation" services, PCC verifies that the "[m]arketing claims [of its verified pharmacies] are truthful and not misleading." PCC sanctions the marketing practices of each of these "pharmacy" affiliates and indeed copies aspects of these affiliates' false and misleading marketing claims on PCC's internet sites.
- 120. PCC describes these affiliates as "Canadian and International Online Pharmacies," "Accredited Canadian and International Online Pharmacies," and represents that by "[u]sing PharmacyChecker.com, it's easy to compare drug prices among trusted international online pharmacies, including licensed Canadian pharmacies...."
- 121. Thus, despite PCC's guarantees that the marketing claims of its verified pharmacies are "truthful and not misleading," a number of these "pharmacies" home pages give consumers the distinct impression that they are ordering drugs from Canada.

- 122. When a consumer searches for a drug via PharmacyChecker.com and PCC's blog sites, the logo of the verified pharmacy intermediary is shown prominently in the results, while the shipping locations only appear in a much smaller and lighter font.
- 123. Some of the misleading claims that PCC and its affiliates make that mislead consumers into believing that the foreign dispensary is a Canadian "pharmacy" that will ship drugs from Canada directly to the consumer's U.S. address include the below examples:
  - a. "PricePro Pharmacy": PCC's website displays the affiliate's name with a prominent Canadian maple leaf logo. At least clicks from DC-based consumers were directed to PricePro Pharmacy from PCC's accredited pharmacies page and drug listing page. The image below is from PCC's website.



While consumers would be right to assume from PCC's site that PricePro Pharmacy dispenses solely from Canada to the U.S., fine print reveals that it may actually dispense from a number of other countries, including India, Mauritius, and Turkey. And in fact, although PCC's website lists PricePro Pharmacy as dispensing drugs from countries including the U.S., the General Manager of PricePro Scripts attested that all of the dispensing pharmacies used by PricePro from 2017 through the present to dispense prescription drugs to consumers who purchase those drugs through the PricePro website are located outside of the U.S. Once linking from PCC's website to PricePro Pharmacy's site, consumers see the prominent front page declaring, in large font: "Certified Canadian Pharmacy" and "Affordable online prescriptions shipped from Canada to the United

States!" This prominent "Canadian" branding, with only a note in fine print at the bottom of the page about dispensing from other international pharmacies, is misleading. A screenshot of this website from May 2021, which PCC represented to consumers as truthful and not misleading, is below.



b. "Your Canada Drug Store": PCC displays this affiliate's "Canadian" branding and maple leaf logo on its platform. At least clicks from DC-based consumers were directed to Your Canada Drug Store from PCC's accredited pharmacies page and drug listing page. In addition to being called Your Canada Drug Store, this affiliate prominently stated in May 2021 on its website, as captured by the internet archive, that it is a "Certified Canadian Prescription Referral Service." A consumer who relies on this would have been surprised to learn that, in the sites FAQs, Your Canada Drug Store states that they are "not a pharmacy," and that, while they connect Canadian orders with Canadian Pharmacies, they also contract with dispensaries in "the UK, New Zealand,

Australia, Turkey, Mauritius, and India." While PCC describes Your Canada Drug Store as a "pharmacy," Your Canada Drug Store claims that it is not in fact a pharmacy. The image below is from PCC's website.



c. "Canadian Prescription Drug Store Rx": PCC's platform also advertises Canadian Prescription Drug Store Rx. Despite its name, this PCC affiliate includes only a fine print disclaimer on its web page that it dispenses from pharmacies outside of Canada, which it claims are "fully licensed and independently verified." Canadian Prescription Drugstore will not even ship drugs to Canada. At least clicks from DC-based consumers were directed to Canadian Prescription Drug Store Rx from PCC's accredited pharmacies page and drug listing page.



d. "Canadian Pharmacy World": this former PCC affiliate claims on its site to be an "online Canadian pharmacy" and "your premium online Canadian source for medications you trust." Canadian Pharmacy World was a PCC affiliate as recently as May 2021. At least clicks from DC-based consumers were directed to Canadian Pharmacy World from PCC's accredited pharmacies page and drug listing page. Like many of PCC's other linked affiliates, Canadian Pharmacy World includes only in fine print hidden at the bottom of its page a vague reference to "international pharmacies and fulfillment centers"

that are approved by the regulatory bodies in their respective countries." Despite representing itself as "your . . . Canadian Source" of drugs, Canadian Pharmacy World also dispenses from Singapore, New Zealand, Australia, India, Mauritius, Turkey, and the UK. The image below is from PCC's website as of May 2021.



e. "Canada Prescription Plus": this former PCC affiliate as of May 2021 stated prominently on its website that it is a "Licensed Canadian Pharmacy" and a "Trusted Canadian Pharmacy." As recently as May 2021, there was no reference on the Canadian Prescription Plus homepage to the fact that this affiliate dispenses from other countries in addition to Canada, including India, Mauritius, Turkey, and Australia. Now, this information is at the bottom of the page in small print. Canada Prescription Plus will not ship drugs to Canada. Upon information and belief, the website blocks<sup>7</sup> Canadian IP addresses, so Canadian customers, or regulators, cannot even access it. Upon information and belief, blocking Canadian customers' ability to even access the website makes them a lower priority for Canadian regulators, and helps them evade the Canadian laws and regulations that it would otherwise need to comply with if it sold to Canadian consumers. Thus, drug sellers like Canada Prescription Plus evade U.S. federal and state pharmacy

<sup>&</sup>lt;sup>7</sup> Upon information and belief, website users transmit their Internet Protocol (IP) address to a website when they visit. With this IP address a website owner can surmise a user's country of origin by cross checking the IP address against the IP addresses purchased by an Internet Service Provider or other third-party databases. This is not a perfect system; consumers can use Virtual Private Networks to change the IP address that a website sees when a consumer visits. A geographic block is a restriction on IP addresses from certain jurisdictions. Therefore if Canadian IP addresses are blocked, a web user with a Canadian IP address will receive an error message instead of the website that he or she is trying to visit.

laws and regulations by operating outside the U.S. and evade Canadian laws and regulations by blocking Canadian consumers. At least clicks from DC-based consumers were directed to Canada Prescription Plus from PCC's accredited pharmacies page and drug listing page. The image below is from PCC's website as of May 2021.



f. "CanDrugstore.com": this former PCC affiliate also extols the benefits of Canadian pharmacies on its site. And despite having "Can" in its name, featuring a Canadian maple leaf in its logo, and representing on its front page that it is "located in Surrey, British Columbia, and is a well-respected Canadian Pharmacy," CanDrugstore.com actually dispenses from a host of other countries in addition to Canada, including Turkey, India, Mauritius, and Australia. Like other PCC affiliates, CanDrugstore.com only mentions "international fulfillment centers" and "dispensaries" in other countries in fine print. CanDrugstore.com will not ship drugs to Canada and, upon information and belief, even blocks Canadian IP Address so that Canadian customers and regulators cannot access it. At least clicks from DC-based consumers were directed to CanDrugstore from PCC's accredited pharmacies page and drug listing page. The image below is from PCC's website as of May 2021.



g. "Maple Leaf Meds": this former PCC affiliate, which has a maple leaf in the logo, dispenses from countries outside of Canada, including Turkey, Mauritius, and India, and will not ship to Canada. The front page of Maple Leaf Meds states in large print: "Reputable Online Canadian Pharmacy – Maple Leaf Medications." Like other PCC affiliates, Maple Leaf Meds only mentions "international fulfillment centers" in fine print. Notably, while PCC represented as recently as May 2021 that Maple Leaf Meds is a "pharmacy," fine print on the affiliate's site reveals that "Maple Leaf Meds is not a pharmacy." At least clicks from DC-based consumers were directed to Maple Leaf Meds from PCC's accredited pharmacies page and drug listing page. The image below is from PCC's website as of May 2021.



h. "Medications Canada": in addition to featuring "Canada" in its name, this former PCC affiliate invited consumers in May 2021 to "Check Canadian Pharmacy Prices." Although Medications Canada also dispenses from India, Mauritius, and Turkey, Medications Canada does not state anywhere on its front page that it dispenses from locations other than Canada. Medications Canada will not ship to Canada and, upon information and belief, even blocks Canadian IP Address so that Canadian customers cannot access it. At least clicks from DC-based consumers were directed to Medications Canada from PCC's accredited pharmacies page and drug listing page. The image below is from PCC's website as of May 2021.



i. Other "Pharmacy Intermediaries" that are or were PCC affiliates purport to ship worldwide, including to customers in Canada, but, upon information and belief, many of these sites block consumers with Canadian IP addresses (and thus actual Canadian customers and regulators). This includes, recently March 2022, as discountcanadadrugs.com, canadianpharmacystore.com, inhalersonline.com, canadacloudpharmacy.com, globalcarerx.com, canadacloudpharmacy.com, drugmart.com, planetdrugsdirect.com, drugmartdirect.com, doctorsolve.com, pharmstore.com, and pharmapassport.com.

# E. Statements that Mislead Consumers about the Safety and Trustworthiness of PCC's Accredited Pharmacies

- 124. PCC misleads consumers regarding the safety and trustworthiness of each of the foreign online drug sellers that it directly profits from in at least two material ways. First, PCC represents to consumers that each such affiliate is safe, trustworthy, and operating in compliance with Canadian and other regulatory requirements when, in fact, this very often is false and misleading. Second, despite PCC's verification guarantee that the "marketing claims" of its pharmacy intermediary partners are "truthful and not misleading," these websites offer consumers a veritable thicket of false and misleading information.
- 125. PCC makes its own false and misleading representations and adopts equally dubious representations made by its drug supplier affiliates for the express purpose of inducing consumers to buy foreign drugs unlawfully and unsafely. PCC advertises these affiliated drug suppliers' prices on PCC's websites, encourages consumers to shop from these affiliated suppliers,

and provides a direct link to the affiliates' websites where consumers are further misled into purchasing what they believe to be safe and legal drugs from PCC "approved" or "verified" "pharmacies." PCC profits directly from this scheme to facilitate unlawful and unsafe drug purchases.

- 126. The front page of PCC's website includes a section purporting to describe PCC values, including "Safety." PCC's front page also features "Pharmacies We Verify," stating that the international online pharmacies that PCC verifies are "vetted for consumer safety" and linking to a "List of Safe Pharmacies." Next to that is a statement about their Verification program: "The PharmacyChecker Verification Program helps consumers verify international online pharmacies to find out if they meet high standards of pharmacy practice."
- 127. These statements are misleading; PCC does not actually verify that its accredited pharmacies are safe, as testified to by PCC's then Vice President of Pharmacy Verification and Information (testimony that "I don't know that it was anyone's job at PharmacyChecker to verify that online pharmacies were safe—including my own."). The affirmative statements that these foreign pharmacies are "safe" and "vetted" are misleading and at odds with the regulatory regime in the United States to ensure pharmacy safety, which includes oversight by the FDA as well as state pharmacy regulatory boards. In fact, as testified to by one of PCC's co-founders, PCC makes no effort to verify (testimony that ). Consumers, used to buying pharmaceuticals in a contained and regulated environment, may be misled into believing PCC's statements that its "accredited" drug suppliers are somehow equivalent in terms of safety, reliability, and legality to their local regulated pharmacy.

- 128. Below the "PharmacyChecker Values" banner on the main page of the PharmacyChecker.com website is a statement with the header "Buying Medication Internationally" that says "Millions of Patients purchase medicine from Canada and other countries each year. You can do so more safely by sticking to PharmacyChecker-accredited pharmacies." There is no mention of legality.
- 129. In a November 25, 2020 posting, which PCC also disseminated to consumers by email, PCC similarly represented that "we know that millions of Americans already use pharmacy websites, located in Canada or elsewhere, to afford their prescriptions. And we pledge to continue to provide those people with the information necessary to do so safely." PCC's statements here both misrepresent the safety of personal importation and its statement that "millions of Americans" personally import foreign drugs misleads consumers into believing that such importation is legal.
- 130. PCC also publishes on its site a slideshow stating that: "Zero times. The FDA has never reported anyone harmed by a medication they ordered from an international pharmacy requiring a valid prescription." This is sourced to a footnote that attributes it to "PharmacyChecker.com research." PCC's statements are designed to and have the effect of misleading consumers.
- 131. The FDA expressly warns consumers about pharmacies that are "located outside of the United States" or that do not have a "U.S. state-licensed pharmacist" available to answer questions, noting that these pharmacies "often sell medicines that can be dangerous because they may: [h]ave too much or too little of the active ingredient you need to treat your disease or condition[;] [n]ot contain the right active ingredient[;] [c]ontain the wrong or other harmful ingredients"; or that medication may not be stored properly.<sup>8</sup>

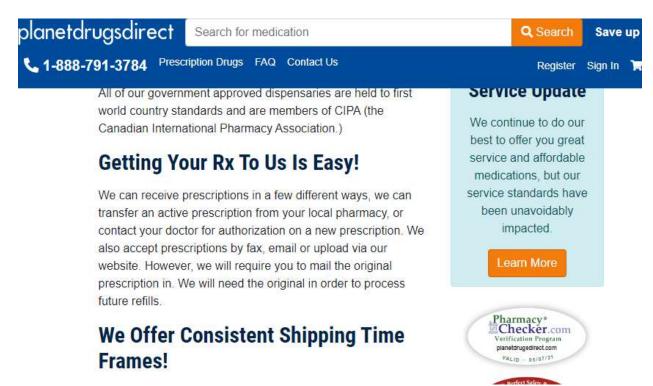
48

 $<sup>^8</sup>$  https://www.fda.gov/consumers/consumer-updates/how-buy-medicines-safely-online-pharmacy.

- 132. The fact is that the FDA has excellent visibility into drugs at all stages of the regulatory "closed system," and only limited visibility into drugs that pass illegally outside of the closed system. The fact that, according to PCC, the FDA has never (1) reported (2) anyone harmed (3) by a medication (4) they ordered (5) from an international pharmacy (6) requiring a valid prescription is so qualified as to be misleading. If the FDA seized counterfeit medication before it got to the consumer, that would not count. If a relative ordered medication for the consumer, that would not count. If the FDA reported someone harmed by medication from an international pharmacy but failed to state whether that pharmacy required a valid prescription or failed to weigh in on the validity of the prescription outside of their jurisdiction, that might not count either.
- 133. The FDA recently issued an import alert for Planet Drugs Direct, calling for the "detention without physical examination" of "Foreign Manufactured Unapproved Drugs Promoted to Individuals in the U.S.," noting that these drugs "present serious safety risk and effectiveness concerns." The list of firms and their products subject to detention includes "Planet Drugs Direct."
- 134. Planet Drugs Direct remained a PharmacyChecker-approved pharmacy as of May 7, 2021, despite the fact that all prescription drug products it sends into the U.S. were then subject to detention without examination. Its website still bore the PCC seal of approval, as seen in the lower right of the screenshot below.

<sup>&</sup>lt;sup>9</sup> While Federal law requires that prescription drugs be dispensed only pursuant to a "written prescription of a practitioner licensed by law" to administer a given drug, *see* 21 U.S.C. § 353(b)(1), in practice, the FDA is not the primary arbiter of prescription validity. That role lies with state regulators.

<sup>&</sup>lt;sup>10</sup> https://www.accessdata.fda.gov/cms ia/importalert 197.html.



- 135. The FDA has repeatedly warned of the dangers of personal importation and of the dangers posed by foreign drugs from unknown sources. The FDA states that consumers should "only buy prescription medication from state-licensed pharmacies located in the U.S." and has identified counterfeit mail-order drugs.<sup>11</sup>
- 136. In addition to conspicuous claims that drugs are from Canada, followed by hidden claims that drugs may in fact be dispensed from other locales (and thus not meet Canadian regulatory standards), PCC and its affiliates go out of their way to hide from consumers even the identities of who is actually supplying the drugs, from where the drugs are in fact sourced, and on what terms the drugs are being sold to consumers. All the while falsely and misleadingly representing to the consuming public that the drugs they will eventually ingest are safe and lawful to acquire.

<sup>&</sup>lt;sup>11</sup> https://www.fda.gov/drugs/drug-safety-and-availability/counterfeit-versions-cialis-tablets-identified-entering-united-states

- 137. Many of PCC's affiliated sellers also promise safety policies, for example recall policies, that simply do not exist. Thus, in the event of a product safety recall from a government regulator, and despite PCC's guarantee that the "marketing claims" of its pharmacy intermediary partners are "truthful and not misleading," consumers who purchase these drugs through PCC and its affiliates would likely never know if their foreign-sourced drug were subject to such a safety recall thus endangering the health of the consuming public. These companies also expressly disclaim any warranties of the merchantability or fitness for purpose of the drugs they sell. This shows that these companies view their promises of safety as essentially empty. Their guarantee of safety ends where taking actual legal and financial responsibility for the products they sell begins.
- 138. PCC's affiliates also go out of their way to hide their own identity—even their corporate identities—to disclaim even the most basic warranties for the pharmaceutical products they sell, to disclaim that they are selling anything at all, and to shift risk onto the consumer.
- 139. This section will highlight certain examples—PriceProPharmacy.com and Canadian Prescription Drugstore—but these practices persist across PCC's "verified" pharmacy affiliates.
- 140. Nearly all of PCC's "verified" pharmacies make similar misrepresentations, despite PCC guaranteeing to consumers that these websites marketing is truthful and accurate and thus will not mislead consumers.

## i. PriceProPharmacy.com

141. PriceProPharmacy is listed on PCC's website as a pharmacy on the accredited pharmacies and drug listing pages, inviting consumers to click through to access PriceProPharmacy's homepage or specific drug page and purchase prescription drugs from abroad.

At least clicks from DC-based consumers were directed to PriceProPharmacy's website

directly from PCC. Upon information and belief, at least some of these referrals from PCC resulted in transactions of unlawful personal importation.

- 142. PCC tells consumers that: PriceProPharmacy.com is a pharmacy, that PriceProPharmacy.com's "Marketing claims are truthful and not misleading," that PriceProPharmacy is an "Accredited . . . Online Pharmac[y]," and that they "sell safe and affordable medication." None of these claims are correct. As noted, PCC does not verify that its affiliates are safe,

  . And among other things, the marketing claims of PriceProPharmacy.com are wildly misleading, with broad disclaimers hidden in the fine print, and PriceProPharmacy disclaims being a pharmacy. PriceProPharmacy.com even disclaims that it sells anything to consumers.
- 143. Their FAQ page also includes a prominent badge that tells consumers "we ship all across the USA." (emphasis added).

#### **US DELIVERY**



- 144. All of these claims are misleading.
- 145. For example, PriceProPharmacy.com tells consumers that it is a "Certified Canadian Pharmacy," that it is an "Online Canadian Pharmacy for U.S. Residents," that their "fulfillment centers" enable consumers to "buy popular Canadian drugs online," that they are a "legitimate and licensed online source for the safest and highest quality brand and generic medication," and that "[1]ocated in the beautiful province of British Columbia in Canada, Price Pro Pharmacy and its supplier affiliates are all fully licensed, verified, and accredited by PCC."

146. Similarly, the "About Us" section of the PricePro website talks about "Our Canadian Pharmacy" and about "ordering cheap medication from Canada through Price Pro," and asking "why order meds from Canada?" There is only one fleeting mention that "PricePro also associates with international pharmacies that are approved by regulatory authorities in their respective countries," but even this is followed by "join millions of happy, money-saving consumers ordering their prescriptions through Canada with PricePro today!"

### 147. It is only in the fine print at the bottom that PricePro says:

PriceProPharmacy.com dispenses prescription medications and over the counter products from Canada through our affiliated Canadian pharmacy which is duly licensed in the province of British Columbia, Canada by the College of Pharmacists of British Columbia. PriceProPharmacy.com also uses affiliated international pharmacies that are approved by regulatory authorities in their respective countries and certified by PharmacyChecker.

These affiliated facilities and international fulfillment centers dispense medications which they acquire in their home countries or internationally from countries like Australia, New Zealand, India, Turkey, United Kingdom, Germany and other European Union member states.

- 148. In other words, once American consumers link from PCC's website to its affiliates page, they are faced with the misleading impression that PriceProPharmacy will send them medication from Canada when, instead, the affiliate can supply drugs from "affiliated facilities and international fulfilment centers" located in other countries, which in turn may have acquired the medication in their home countries or internationally from "countries like" Australia, New Zealand, India, Turkey, United Kingdom, Germany and other European Union member states.
- 149. Despite prominent references to Canada, PriceProPharmacy dispenses from "supplier affiliates" all over the world, including Mauritius, India, and Turkey. In fact, the General Manager of PricePro Scripts attested that all of the dispensing pharmacies used by PricePro from 2017 through the present to dispense prescription drugs to consumers who purchase those drugs

through the PricePro website are located outside of the U.S. These supplier affiliates are not required—under PCC's program—to follow Canadian pharmacy standards.

- 150. In addition, PriceProPharmacy elsewhere denies being a pharmacy at all.
- 151. Their "Terms of Sale" page, hidden at the bottom, clearly states that "PriceProPharmacy (PriceProPharmacy.com<sup>TM</sup>) is a marketing entity located in Surrey, British Columbia, Canada. PriceProPharmacy.com<sup>TM</sup> is not engaged in conducting sales, but rather engages in the business of facilitating sales transactions on behalf of authorized pharmacies both within Canada and internationally."
- 152. In other words, they are a middleperson. They are not a pharmacy. They do not ship drugs. Some other unidentified person or entity, not verified by any legitimate governmental or other agency, that obtained the subject drugs from undisclosed sources outside the FDA's "closed system," ships these drugs internationally to U.S. consumers who are led to believe—from PCC's and PriceProPharmacy's sites—that they are lawfully obtaining drugs from a *Canadian pharmacy* that has been "verified" by PCC. None of these consumer expectations, created via PCC's false and misleading commercial marketing, are satisfied.
- 153. What's more, despite PCC's guarantee that their affiliates' websites "sell safe and affordable medication," these websites claim they are not even in the sales business.
- 154. A consumer dealing with PriceProPharmacy could reasonably believe that he or she is receiving drugs from PriceProPharmacy that conform to Canadian standards. Unless he or she reviews the contract of adhesion terms and conditions—which, upon information and belief, very few consumers do—he or she would have no idea that PriceProPharmacy is not a pharmacy.
- 155. Even these terms and conditions are far from straightforward. For example, they include a limited power of attorney where the consumer agrees to disclose his or her personal

health information to a seemingly unrelated company—CanadaDrugs.com. There are no other mentions of CanadaDrugs.com on PriceProPharmacy's website, and no information provided to tell a consumer *why* his or her personal health information is being disclosed to this seemingly unrelated third party. In fact, Canada Drugs was convicted of selling mislabeled and counterfeit drugs in the United States in 2018.

- 156. Canada Drugs and a number of related entities were sentenced to forfeit \$29 million, pay a fine of \$5 million, and to "permanently cease" illegal operations and surrender domain names to the United States after being convicted and sentenced in the United States District Court for the District of Montana for selling counterfeit and misbranded prescription drugs.
- 157. Executives of CanadaDrugs.com were also convicted and required to pay fines and serve sentences of probation and home confinement.
- 158. The indictment of CanadaDrugs.com notes that "CANADA DRUGS purchased its inventory from questionable sources and ultimately sold counterfeit versions of the drugs Altuzan and Avastin to physicians in the United States."
- 159. It is not at all clear why PriceProPharmacy would need to share consumer data with CanadaDrugs.com, but it is clear that, while verified as safe and trustworthy by PCC, CanadaDrugs.com was a business that did real harm by obfuscating the sources of its drugs and selling misbranded and counterfeit drugs, including counterfeit cancer drugs for use by United States patients.
- 160. A consumer—without significant diligence—will not even know that their information is being shared with a criminal organization that sold counterfeit cancer drugs into the United States.

- dealing with despite PCC's stamp of approval for PriceProPharmacy and PCC's broad claims up front about safety, quality, and sourcing. PriceProPharmacy.com relies on buried disclaimers and secret supplier identities to protect it from actually having to take responsibility following the law, communicating with consumers about subsequent developments such as drug safety recalls, or even that consumers are buying what they think they are buying or dealing with who they think they are dealing with.
- 162. Further, PriceProPharmacy, despite prominently claiming to offer the "safest and highest quality" drugs, then expressly disclaims all warranties for the products it sells, including "the implied warranty of merchantability and fitness for a particular purpose."
- 163. In other words, PriceProPharmacy prominently promises that consumers are getting the best possible goods, and then—buried in fine print—disclaims all responsibility for giving consumers adequate goods.
- 164. They also tell consumers that they "offer a Recall Policy" and include a term that the "customer agrees to review the Recall Policy each time it submits an order." Upon information and belief, PriceProPharmacy.com does not make a recall policy available to consumers for them to review.
- 165. In addition to manually scouring the PriceProPharmacy.com website, which did not turn up such a policy, an internet search of the term "recall policy' inurl:pricepropharmacy.com" reveals that the only instances of the term "Recall Policy" on PriceProPharmacy's website are in the Terms of Sale and Terms of Use for the site.
  - 166. There is, in other words, no actual recall policy.

- 167. It simply cannot be the case that a "legitimate and licensed online source for the safest and highest quality medication" has no plans to inform consumers about critical safety recalls. Even drugs closely scrutinized by regulators are recalled from time to time. But because drugs sold via PCC affiliates like PriceProPharmacy are outside the FDA's "closed system" and the safety assurances that the system supports, patients are at risk. This risk is directly attributable to PCC's false and misleading representations and PCC's facilitation of purchases from entities like PriceProPharmacy.
- 168. There are more terms that go to the very heart of the problem with PCC's misleading business model—consumers who order from PCC have no idea who they are actually dealing with; anonymous lawbreakers simply use PCC to launder their reputations and hide their identities; and consumers who buy drugs via PCC and its intermediaries are taking a significant risk.
- 169. For example, clause 17 of the terms of sale states that "PriceProPharmacy.com™ is a Canadian business registered in the Province of Manitoba."
- 170. An entity search via the Manitoba Companies Office reveals that there is no registered company under "PriceProPharmacy.com," "Price Pro Pharmacy," or even "Price Pro." There is a Price Pro Homes Ltd.
- 171. The Victoria British Columbia Corporate registry does show that at one point a "PriceProPharmacy.com, Inc." was registered, but it changed its name to "Quantus Care Inc." in 2018.
- 172. Quantus Care Inc. does appear to be a registered business in British Columbia—but not Manitoba—and nowhere does the corporate entity appear on the PriceProPharmacy.com website.

### ii. Canadian Prescription Drugstore

- 173. Canadian Prescription Drugstore is also listed on PCC's website as a pharmacy on the accredited pharmacies and drug listing pages, inviting consumers to click through to access Canadian Prescription Drugstore's homepage or specific drug page and purchase prescription drugs from abroad. At least clicks from DC-based consumers were directed to Canadian Prescription Drugstore's website directly from PCC. Upon information and belief, at least some of these referrals from PCC resulted in transactions of unlawful personal importation.
- 174. PCC makes similar misrepresentations on its websites about Canadian Prescription Drugstore and facilitates consumer purchases by: (i) recommending Canadian Prescription Drugstore to consumers; (ii) making false and misleading statements about Canadian Prescription Drugstore's safety and business operations; and (iii) then directly linking consumers eager to purchase foreign pharmaceuticals with Canadian Prescription Drugstore's internet website.
- 175. PCC has generated income from Canadian Prescription Drugstore including by verifying Canadian Prescription Drugstore and facilitating consumer purchases of foreign drugs via Canadian Prescription Drugstore's internet marketplace. Upon information and belief, Canadian Prescription Drugstore uses PCC's Pharmacy Listing and Price Listing Services.
- 176. PCC's website states that "Pharmacy Listing and Price Listing programs are feebased. A participating online pharmacy can cancel at any time after an initial three-month listing period. The online pharmacy will receive monthly click-thru reports and can set spending limits."
- 177. In short, the more successful PCC is at facilitating consumer purchases from Canadian Prescription Drugstore and other foreign online drug suppliers through its false and misleading representations, the more money PCC makes.

- 178. PCC also tells consumers that Canadian Prescription Drugstore's marketing claims are "truthful and not misleading," that Canadian Prescription Drugstore is "legitimate," "safe," or "reputable," and even that it is a pharmacy. Consumers need to look past plain, straightforward, and false statements on the face of Canadian Prescription Drugstore's website and navigate a web of ambiguous and hidden disclaimers and legalese to even learn part of the truth about Canadian Prescription Drugstore's business model: that they are not a pharmacy, that they are not Canadian, and that they disclaim any warranty that the drugs they dispense are safe or that the pharmacy services they provide are sufficient.
- Drugstore are "truthful and not misleading," and even their claims that Canadian Prescription Drugstore—like all their verified pharmacies—is "reputable" and legitimate, Canadian Prescription Drugstore engages in a practice of misleading consumers about the quality and safety of the medication it is selling, while at the same time, and like PCC, relying on buried, half-hearted and misleading disclaimers seeking to evade responsibility for the product they are selling, denying they are selling anything at all, and denying that they have any obligations to consumers.
- 180. On the face of their website, Canadian Prescription Drugstore tells customers that it provides "Trust, Savings, Safety—Since 2004," and that it has an "industry leading six point guarantee," including a "Safety" guarantee that "Medications [are] dispensed only by fully licensed pharmacists," and a Quality guarantee of "Genuine brand and generic products shipped in original manufacturer's packaging."
- 181. As of May 2021, they also told consumers that they are a "pharmacy," (now the website says "pharmacy referral service"), they are "one of the oldest and most trusted," and that

"our fully licensed pharmacists and pharmacy technicians ensure safe and professional care of your orders."

- 182. It is only in tiny, lighter font, appearing below a British Columbia address, that they note that they dispense medication from "pharmacy partners around the world," including India, Turkey, Singapore, and England.
- 183. Notably, this list is different from the list of dispensing countries PCC represents Canadian Prescription Drugstore dispenses from on PCC's website. PCC's list includes Mauritius and does not include England or Singapore.
- 184. Canadian Prescription Drugstore also tells consumers that "many legal experts disagree with the FDA's position [that virtually all importation of prescription drugs is a violation of the law] . . . stating that such importation is permitted under certain federal and state laws," and that "[t]he FDA itself provides the public information on how to import medications safely." These statements are false.
- 185. In other words, Canadian Prescription Drugstore goes out of its way to make consumers believe that clear law is actually a grey area. Ironically it does this in hard-to-read grey text on grey background.
- 186. Even Canadian Prescription Drugstore's privacy policy is designed to make it seem like all orders come from Canadian pharmacies, stating:

When you place your order with Canadian Prescription Drugstore, we refer your prescription along with your personal contact information and medical history to our fully licensed Canadian Online Pharmacy for doctor review and dispensing. Under very strict Canadian Online Pharmacy regulations, our pharmacy and doctors are obliged by law to keep your information under confidence, to be used exclusively for the purposes of approval and dispensing of your prescription order.

187. In its terms of use, Canadian Prescription Drugstore calls itself "an online pharmacy prescription drug referral service," and asks consumers to verify that they are of age to purchase

"Canadian Online Pharmacy Medications." This language is designed to lead consumers to believe that they are: (1) dealing with a pharmacy; and (2) purchasing drugs that are either from Canada or subject to regulation by Canada. Neither is true.

- 188. PCC also describes Canadian Prescription Drugstore as a "pharmacy," requiring that consumers find a hidden link to reveal that they are actually just a pharmacy intermediary. As of May 2021, Canadian Prescription Drugstore only disclosed in fine print at the bottom of its website to customers linking to its site from PCC that it "is a prescription drug online pharmacy referral service that partners with licensed pharmacies for Canadian Prescriptions."
- 189. Upon information and belief, it is unlawful in all or nearly all states in the United States for an entity to hold itself out as a pharmacy when not licensed pursuant to that state's pharmacy regulatory regime.
- 190. Like PriceProPharmacy.com, Canadian Prescription Drugstore also "disclaim[s] any representations and warranties of its prescription drugs or Pharmacy services including medication warranties of merchantability, prescription drug fitness and usefulness for a particular online prescription purpose."
- 191. Thus, not only does Canadian Prescription Drugstore refuse to stand behind the drugs consumers buy from it despite its so-called "six point guarantee," it also refuses to stand behind any "Pharmacy services" it provides.
- 192. In the terms and conditions section it hedges still more, telling consumers that, rather than being a pharmacy or directly providing pharmacy services, it "specializ[es] in the business of assisting consumers both within the USA and internationally [to] pursue prescription pharmacy services."

- 193. Notwithstanding PCC's direct statement to its customers that CanadianPrescriptionDrugstore.com is a safe and legal source from which PCC customers can obtain foreign drugs, CanadianPrescriptionDrugstore.com does not even pretend to have a recall policy. Thus, notwithstanding PCC's representations to consumers that this internet "pharmacy" is safe and legal and PCC linking consumers to make purchases from this affiliated site, a consumer who bought a drug that was the subject of a safety recall would likely never receive notice from either PCC or the affiliated online drug facilitator that the patient was potentially in grave danger.
- 194. The bottom line is that consumers really have no idea who they are dealing with when they purchase from this and other affiliates of PCC, which PCC falsely and misleadingly verifies as safe and trusted and then encourages consumers to purchase drugs from them via a direct PCC link.

# III. PCC's False and Misleading Claims About NABP

- 195. Since 1999, with the launch of its VIPPS program, NABP has worked tirelessly to enhance consumer access to safe, legal online pharmacies.
- 196. This has meant giving consumers a way to avoid "rogue" pharmacies and bad actors that purport to sell prescription drugs online, but which do not follow the laws of the jurisdictions into which they are selling.
- 197. Companies including payment processors and ad-sellers can face significant civil and even criminal liability for connecting consumers to these rogue lawless entities.
- 198. As a result, NABP has taken several different approaches to help allow online pharmacy to become a safe, competitive marketplace for law-abiding sellers. This includes verification of pharmacies that operate safely and lawfully online and a not-recommended sites list to screen out pharmacies and entities that purport to be pharmacies but do not follow the applicable regulatory scheme.

- 199. NABP has also worked with a variety of stakeholders and ICANN to create the .pharmacy top-level domain, which is available to any online pharmacy that meets the requirements.
- 200. In 2013, PCC's co-founder and then-Vice President traveled to Washington, D.C. and testified to Congress. In his testimony, PCC's co-founder disparaged NABP as "pharmaceutical industry-funded," engaging in "scare campaigns conflating all non-U.S. pharmacies with rogue pharmacies," and at best suggested that NABP was intentionally "thwart[ing] Americans from accessing affordable medication" to the detriment of patients.
- 201. In February 2015, PCC's co-founder and then-Vice President again disparaged the NABP in Washington, D.C., this time in comments PCC submitted to both the Senate Committee on Health, Education, Labor and Pensions and the House Committee on Energy Commerce. There, PCC disparaged the NABP by falsely alleging: "The NABP's website states that it is an 'independent and impartial' organization, but its leadership, affiliations and funding sources cast serious doubt on that assertion. The NABP, like its member pharmacy boards, are governed by owners and executives of U.S. pharmacies." PCC also falsely alleged that NABP's conduct is likely to "scare" consumers away from safe medication. PCC's submissions to lawmakers in Washington also falsely alleged that NABP's practice of classifying certain online foreign pharmacies as "not recommended" misleads consumers.
- 202. PCC has continued its malicious attacks specifically against NABP through its PharmacyChecker.com and blog sites. As shown herein, PCC's web presence is accessed thousands of times by Washington, D.C. residents and consumers of PCC's services. PCC's false and misleading statements include those alleging that NABP bears responsibility for the opioid crisis or that NABP is responsible for pharmacy errors. PCC has published numerous direct attacks

against the NABP and its programs, including NABP's .pharmacy program that PCC compares to its own verification program and the Not Recommended Sites list, that are false and misleading. PCC falsely claims or suggests that:

- NABP is a "front group" for "Big Pharma;"
- that NABP's Not Recommended Sites, VIPPS/Digital Pharmacy Accreditation, and
  .pharmacy programs (unlike PCC's verification program) are untrustworthy due to
  unspecified "commercial interests," "industry funding," or even "potential[] pressure from
  the FDA;"
- that NABP wrongly conflates rogue pharmacies with "safe" international online pharmacies;
- that NABP is somehow involved in "backwards partnerships" to "censor" online pharmacies; and
- that NABP is somehow "endangering patients" and confusing them into purchasing more counterfeit drugs.
- 203. These statements falsely undermine NABP's reputation and consumer trust and confidence in NABP's programs, activities, and indeed in the integrity of the organization itself.
- 204. PCC's motivation is unmistakably economic in nature. PCC uses these false claims to drive consumers away from safe domestic pharmacies and services like NABP's that accredit safe domestic online pharmacies and towards riskier foreign pharmacies that PCC "verifies." PCC's blog prominently links to PharmacyChecker.com and gives consumers the option to directly search for drug prices via PCC's "accredited" unlawful foreign pharmacy intermediaries. PharmacyChecker.com similarly links to and maintains a dedicated page for "Blog News," providing an up-to-date list of blog entries and links to the entries. PharmacyChecker.com and

PCC's blog are one and the same—merely different pages of PCC's web presence, which is singularly devoted to commercially exploiting U.S. consumers unlawful importation of drugs.

- 205. PCC has used its blog to make false, misleading, and disparaging statements about NABP to undermine NABP's reputation and NABP accreditation services that PCC claims to be directly competitive to PCC's "verification" service, while guiding consumers to instead rely on PCC's "verification program" and unlawfully purchase foreign drugs via PharmacyChecker.com.
- 206. For example, on June 4, 2020, PCC published a post titled "NABP and Opioid Death in the U.S." claiming that NABP and its accredited pharmacies "are complicit in the deaths of hundreds of thousands of Americans from opioid drugs" and that NABP "ignored the opioid crisis." It also claims that NABP was somehow complicit by association with wholesale distributors for their alleged role in the opioid crisis because of NABP's alleged deficient wholesaler accreditation programs. These allegations and implications are scurrilous and false. Statements like these are very damaging to a non-profit organization whose mission includes devotion to fostering patient safety.
- 207. PCC also claimed, on February 7, 2020, that NABP "isn't paying much attention to medication errors at U.S. pharmacies" and implied that NABP and verified pharmacies are not protecting public health and failing to catch medication errors.
- 208. On July 24, 2019, PCC compared its own "verification tool" to NABP's so-called "Pharmaceutical Industry-Funded" service. PCC explicitly called its verification tool "a critical alternative to the National Association of Boards of Pharmacy (NABP) dot pharmacy (.pharmacy) program," going on to disparage NABP's .pharmacy program as one which. was "funded by pharmaceutical companies and excludes safe international online pharmacies." "[T]he NABP and

other groups funded by drug companies engage in public information campaigns scaring Americans against buying lower-cost medicine online from another country."

- 209. Like the others, PCC's July 2019 post was surrounded by commercial links enabling and encouraging patients to purchase and import foreign drugs through PCC and its accredited sites.
- 210. PCC has also repeatedly attacked the integrity of NABP's VIPPS/Digital Pharmacy Accreditation program, NABP's Not Recommended Sites list, and the NABP organization itself, while promoting its own programs and services. As described above, PCC's "verification" is fundamentally different from the services offered by NABP, but PCC uses misleading statements to make consumers wrongly believe that they are comparable. PCC accredits international pharmacies without any guarantees that these pharmacies comply with the laws of the jurisdictions they are selling from or selling into. NABP, through its VIPPs/Digital Pharmacy Accreditation Program, only accredits domestic pharmacies and requires that—among other things—these pharmacies be in compliance with any applicable state and federal law.
- 211. On the PCC page titled "Consumer Safety Guide to Online Pharmacies," PCC states that, "[i]n the case of the NABP . . . programs safe international online pharmacies are wrongly viewed as 'rogue' or 'unapproved' we believe due to commercial interests of U.S. pharmacies, pharmaceutical industry funding, and potentially pressure from the FDA."
- 212. A PCC blog post from August 16, 2019 discussing PCC's lawsuit against NABP and other co-defendants bears the title, "PharmacyChecker vs. Big Pharma Front Groups and Allies."
- 213. A PCC blog post from July 26, 2019 calls for consumers to "Verify Online Pharmacies if Going International with PharmacyChecker Alternative to NABP's Program." In

this post, PCC states: "NABP-approved pharmacy sites are too expensive for so many. Folks need an alternative to this pharmaceutical industry-funded program."

- 214. PCC further states that "[u]nfortunately, the NABP's initiative might confuse consumers about online pharmacy safety and affordability." PCC then tells consumers, "For those who need the international pharmacy option, Americans can count on PharmacyChecker.com."
- 215. A PCC blog post from April 25, 2019 titled "Do Google & Bing censor online pharmacy search results? Pharmaceutical companies have called for censorship" claims that Google and Bing rely on NABP's Not Recommended Sites and pharmacy program to perpetrate the so-called "censorship" against "online pharmacies."
- 216. A February 6, 2019 PCC blog entry contains the section heading, in large font, "Bing's Backwards Partnership with the NABP." PCC states:

[T]he NABP's NRL also includes safe international online pharmacies that are accredited and monitored by PharmacyChecker, and there are still countless rogue websites that are not on their list. **The result**: when people search Bing looking to buy medicine online, they are warned against buying from sites that are proven to sell real, lawfully-manufactured medicines and end up buying counterfeit drugs from a rogue site that lacks Bing's warning. (emphasis in original).

- 217. PCC also stated: "Bing's System Encourages People to Order Counterfeit Medications." This section claims that Bing's "system" "scare[] [patients] away from online pharmacies that can help them and into the arms of a rogue online pharmacy." The section goes on to state, "[t]he head of the NABP, Carmen Catizone, should know that this is wrong and endangering patients." PCC's statements that NABP and it's then Executive Director are complicit in encouraging consumers to buy counterfeit medications and scaring consumers to rouge pharmacies is false and misleading and injurious to NABP.
- 218. PCC has also made efforts to spread misinformation in the ICANN ecosystem both about NABP and about importation. For example, PCC funds the Prescription Justice Institute

("PJI"), which recently put out what it calls the "Brussels Principles." In creating these Principles, PJI claimed that it worked with "companies, internet policy experts, NGOs, and Trade Associations," and that they want to deter "dangerous rogue online 'pharmacies."

- 219. Upon information and belief, PCC has made overt and hidden efforts to harm NABP's reputation within the ICANN ecosystem. For example, PCC recently attacked NABP in a discussion of .pharmacy falsely claiming that "NABP and other groups funded by drug companies engage in public information campaigns scaring Americans against buying lower-cost medicine online from another country." The article also claims that NABP's administration of the domain excludes "safe international online pharmacies, including licensed Canadian pharmacies, that sell to Americans." As explained above, PCC's claims that international online pharmacies—particularly the pharmacies it verifies—are safe or "licensed" are misleading.
- 220. These attacks can be particularly harmful because ICANN is an international organization; its constituents, members, and leadership are often not familiar with laws regarding the practice of pharmacy or importation. ICANN is an internet-infrastructure-focused organization, not a pharmacy-focused organization. Educating these members in spite of a constant onslaught of misleading claims from PCC and its allies costs NABP both time and money.
- 221. NABP has had to divert resources to countering PCC's false narratives that its socalled "verified" pharmacies are "safe," "trusted," "technically legal," or that individual consumers will not face sanction for unlawful importation.
- NABP has also had to divert resources to countering PCC's false attacks against NABP. For example, each and every so-called "pharmacy-intermediary" that PCC has verified is on NABP's not-recommended sites list. These intermediaries sell and/or process payments for drugs that are dispensed at non-FDA regulated and/or undisclosed dispensaries all over the world

with pharmacy standards that are different from the U.S., and jurisdictions like Mauritius, Barbados, Turkey, and India, where pharmacy standards (and export standards in particular) fall well short of U.S. standards. They squarely fit within the criteria for NABP's not-recommended sites list because they sell pharmaceuticals in a manner not consistent with state and/or federal law, and/or are clearly inconsistent with NABP's standards.

223. The conduct and statements alleged herein are not an exhaustive list—PCC has engaged in similarly false, misleading, and deceptive acts throughout its existence, including making similarly false and misleading statements throughout its website, blog, and elsewhere.

# IV. Harm to NABP and Consumers, Including in Washington, D.C.

- 224. NABP has been harmed by PCC's false and misleading claims about NABP.
- 225. First, NABP has had to divert resources from its core mission to respond to false and misleading attacks against NABP from PCC both before and increasingly after the decision to add PCC to the not-recommended sites list.
- 226. For example, NABP has had to pay a consulting firm to help navigate the ICANN ecosystem. As part of that effort, the firm has, on NABP's behalf, had to respond or escalate to NABP both direct and indirect attacks on NABP from PCC, which costs NABP both time and money.
- 227. NABP has also often had to spend substantial time during important meetings regarding illegal online pharmacies and commercial use of their services explaining at the outset that contrary to the disparaging comments made about NABP, NABP in fact works on behalf of pharmacy practice regulators, not "big pharma."
- 228. NABP is a non-profit, and this resource diversion has harmed and continues to harm NABP's ability to carry out its core public health protection mission.

- 229. In addition to expending resources to address PCC's attacks on NABP's good will and standing, NABP has had to respond to claims from consumers who have been misled by PCC's false and misleading claims about personal importation of prescription drugs, some of whom reached out directly to NABP. For example, NABP has had to respond to an inquiry from a physician about a website that was unlawfully selling pharmaceuticals into the United States and which had been "verified" by PCC.
- 230. NABP staff typically devote resources almost every week responding to consumer questions that—upon information and belief—arise out of misleading information from PCC.
- 231. NABP was also forced to devote staff and contractor time—dozens of person-hours—and other resources to determining whether PCC itself violated NABP policies—and possibly state or federal law relating to the sale and dispensing of prescription drugs (including aiding and abetting violations of the FDCA or conspiracy to violate the FDCA).
- 232. During the relevant time period, American consumers, including residents of Washington, D.C., have visited and, after consuming the information PCC provides on its "verified" pharmacies regarding, inter alia, the safety and legality of personal importation, clicked through from PCC's website to its "verified" pharmacies over with over clicks originating from consumers in Washington, D.C. Upon information and belief, an average conversion rate suggests that these clicks on average would lead to as many as unlawful personal importation instances nationwide and as many as in Washington, D.C.
- 233. Consumers are harmed by false beliefs about the safety of prescription drugs sold by the "verified pharmacies" to which PCC directs them and from which PCC encourages consumers to purchase foreign prescription drugs. The dangers of non-FDA approved

pharmaceutical manufacturing are well known, and PCC cannot—and has testified that it does not—guarantee safety or that its "verified" pharmacies comply with U.S. law.

- 234. Consumers are also harmed by false beliefs about the allowability and legality of importation; not only do they risk prosecution—or at least law enforcement contact—but there is a serious risk that their medication will be confiscated or delayed at the border (leaving them out the purchase price or forcing them to go without), or that they will receive medication that is different from the FDA-approved equivalent, has lost potency due to improper handling or storage, or was improperly dispensed by someone other than a pharmacist licensed in the relevant jurisdiction.
- 235. NABP has had to devote time and resources fighting these pernicious myths from PCC and directing consumers to sites that conduct pharmacy safely. For example, its staff and consultants spent person-hours they would otherwise have spent on other activities preparing a staff member to Berlin to attend the Internet Governance Forum to respond to PCC's false and misleading claims about online pharmacy in and in conjunction with the PCC-backed "Brussels Principles."
- 236. PCC's efforts have also undercut efforts by NABP to ensure patient safety by supporting a marketplace for safe, lawful, legitimate online pharmacy.
- 237. The internet can be the wild west. Individuals and companies can mask their identities and fleece consumers for various ends, ranging from brazen or subtle scams, gathering of personal information, to selling consumers products that are not what they purport to be.
- 238. There are thousands of bad actors on the internet that purport to be pharmacies that are actually not licensed, that dispense unregulated drugs, or that even dispense without the legal right to dispense to the consumers that they are targeting.

- 239. It was not a foregone conclusion that a marketplace for safe, legal, legitimate online pharmacy could exist in this environment.
- 240. NABP has made it its mission to support a market for online pharmacy by giving consumers tools to differentiate legitimate online pharmacies that can lawfully sell to them and other websites that purport to be pharmacies but that do not comply with the laws and rules applicable to pharmacies.
- 241. PCC's pernicious business model, and the false and misleading statements it makes to support its business model, threaten both the very existence of a legitimate market for online pharmacy and NABP's work to support that market and ensure patient safety.
- 242. PCC built its business model around blurring the line and misleading consumers about the difference between safe, lawful online pharmacies and websites that purport to be pharmacies but pick and choose which aspects of pharmacy and pharmaceutical regulation that they comply with.
- 243. NABP has had to devote time and money to correct consumer misapprehensions caused by PharmacyChecker, and to protect the very existence of a legal, safe marketplace for online pharmacy.
- 244. This includes, among other things, expenditure of resources—including person-hours by NABP's Executive Director—surrounding the decision to add and maintain PharmacyChecker.com to the Not Recommended Sites list.
- 245. NABP has also had to devote employee time reviewing websites that PCC has verified as part of its broader effort to maintain the Not-Recommended Sites list. This includes sites like Planet Drugs Direct, which was the subject of an FDA import alert.

### Counterclaim

# (Violation of the D.C. Consumer Protection Procedures Act, D.C. Code § 28-3904)

- 246. Counterclaim-Plaintiff realleges by reference the counterclaim allegations in Paragraphs 1 through 245 above.
- 247. Counterclaim-Defendant has engaged in unfair or deceptive trade practices in violation of D.C. Code § 28-3904, including the provisions thereof immediately below.
  - 248. Section 28-3904 provides, in relevant part:

It shall be a violation of this chapter for any person to engage in an unfair or deceptive trade practice, whether or not any consumer is in fact misled, deceived, or damaged thereby, including to:

- (a) represent that goods or services have a source, sponsorship, approval, certification, accessories, characteristics, ingredients, uses, benefits, or quantities that they do not have;
- (b) represent that the person has a sponsorship, approval, status, affiliation, certification, or connection that the person does not have;
- (c) represent that goods are original or new if in fact they are deteriorated, altered, reconditioned, reclaimed, or second hand, or having been used;
- (d) represent that goods or services are of particular standard, quality, grade, style, or model, if in fact they are of another;
- (e) misrepresent as to a material fact which has a tendency to mislead;
- (e-1) Represent that a transaction confers or involves rights, remedies, or obligations which it does not have or involve, or which are prohibited by law;
- (f) fail to state a material fact if such failure tends to mislead;
- (f-1) Use innuendo or ambiguity as to a material fact, which has a tendency to mislead;
- (g) disparage the goods, services, or business of another by false or misleading representations of material facts; ...and
- (t) use deceptive representations or designations of geographic origin in connection with goods or services.

- 249. Counterclaim-Plaintiff brings its claims on behalf of itself and the consumers and general public of the District of Columbia under D.C. Code § 28-3905(k)(1)(C)-(D).
- 250. Among other things, Counterclaim-Defendant has made false and misleading statements about the nature, quality, and characteristics of NABP, as well as the nature, quality and characteristics of the "verification" and "accreditation" services NABP provides.
- 251. PCC's conduct, described above, constitutes false and misleading descriptions of fact and false and misleading representations about the nature, characteristics, quality, and geographic origin of the goods and services provided by PCC and the affiliated drug suppliers that PCC claims to "verify." Specifically, PCC makes an affirmative effort to mislead ordinary consumers, including those in Washington, D.C., about the legality of personal importation, about the origin of pharmaceuticals sold by its so-called "verified" pharmacies, about the regulatory status of the pharmaceuticals sold by foreign pharmacies, about the origin of goods sold by foreign pharmacies and equivalence to FDA-regulated pharmaceuticals, and about the origin and equivalence of pharmaceuticals sold by domestic pharmacies to non-FDA-regulated foreign pharmaceuticals.
- 252. Counterclaim-Defendant's statements and commercial efforts about the legality of drugs sold by its foreign but "verified" pharmacies can and do mislead consumers about the safety of drugs sold through those pharmacies, the regulatory status of drugs sold through those pharmacies, and even the origin of drugs sold through those pharmacies.
- 253. Testimony by PCC's co-founder and PCC's Vice President of Pharmacy Verification and Information from 2016-2019 established that PCC in fact does not "verify that online pharmacies are safe" and is
- And, for example, former PCC-verified "Your Canada Drug Store," dispenses

pharmaceuticals from, among other places, India, Mauritius, New Zealand, and Turkey. "Canadian Prescription Drugstore" will not ship drugs to Canada. In addition, while it may be true that private citizens are not ordinarily charged for importing drugs, it is misleading to state that these individuals "are not pursued or prosecuted." Consumers are also misled into believing, for example, that drugs from Mauritius are subject to the same regulatory rigors as drugs from Canada, or that drugs from Canada are the same as drugs sold in the U.S. Even the idea that consumers can identify and compare "verified pharmacies" on PCC's website is misleading. Consumers must click through at least three web pages to learn that all of the so-called Pharmacies on PCC's list of "Accredited Canadian and International Online Pharmacies" are in-fact "Pharmacy-Intermediaries" and not pharmacies at all. The names and licenses of every single "Verified Dispensing Pharmacies" are hidden from consumers.

- 254. Defendant's use of the terms "Verified" and "Accredited" are likely to cause confusion among consumers who may believe that these pharmacies are operating lawfully or that PCC's verification program is the equivalent of NABP's .pharmacy program. Consumers must scroll to the bottom of the page to find a hidden-by-default disclaimer that claims first that Ordering Medication from online pharmacies is legal, but then that it is "technically not legal" for individuals to import prescription drugs. Further, PCC claims that all its verified pharmacies have orders reviewed by a "licensed pharmacist and dispensed from a licensed pharmacy," obfuscating who licenses these pharmacies and pharmacists and what they are licensed to do—in almost no cases are they licensed in accordance with state and federal law to dispense prescription drugs to U.S. Consumers.
- 255. These misrepresentations by Counterclaim-Defendant were made with the express intention of confusing, misleading, and deceiving members of the public, including those in

Washington, D.C., into believing that: (1) PCC's verified pharmacy intermediaries and their dispensaries are safe, trusted, and the equivalent of regulated U.S. pharmacies selling FDA-regulated drugs; (2) NABP is a shill for "big pharma" and indifferent to or neglectful of the genuine safety requirements of pharmacy and the needs of consumers; (3) that NABP is otherwise disreputable or untrustworthy.

- 256. Counterclaim-Defendant has also failed to give consumers material information about the legality and quality of unlawfully imported drugs available through PCC's pharmacy intermediaries.
- 257. PCC has also represented that transacting with these pharmacy intermediaries will give consumers rights to goods, even though the right to those goods is prohibited by law—namely unlawfully imported, non-approved, and mislabeled foreign pharmaceuticals.
- 258. Consumers have also been misled about the potential benefits in the form of savings they would receive from purchasing their medications through PCC which would influence their purchasing decisions.
- 259. NABP's mission is, in part, focused on protecting public health and when consumers do choose to buy pharmaceuticals online, ensuring consumers do so safely and legally. NABP is engaged in—among other things—through its various pharmacy accreditation programs, making safe, lawful online pharmacy available to consumers and creating the circumstances in which a true competitive online pharmacy market can thrive.
- 260. Counterclaim-Defendant's conduct, described above, in making false, disparaging, and misleading statements about NABP—in statements to the media, statements to the public, and articles published on Counterclaim-Defendant's website and blog—is likely to mislead, or have misled, consumers including those in Washington, D.C., as to the nature, quality, and

characteristics of the services authorized by NABP, specifically the safety, scrupulousness, and legality of NABP's VIPPs/Digital Pharmacy Accreditation program and of pharmacies verified pursuant to that program.

- 261. Counterclaim-Defendant's statements and commercial efforts are likely to cause, and have caused consumers to believe that NABP is indifferent to and complicit in the opioid crisis, that NABP is part of an effort to "scare" patients away from affordable medication, and that NABP has independently made a policy choice to exclude "safe international online pharmacies" from selling into the United States.
- 262. NABP has expended resources and diverted staff time to combatting PCC's false statements about NABP, about the safety and legality of personal importation, about the (lack of) equivalence of FDA-approved drugs and non-approved or misbranded foreign drugs, and about the safety and legality of PCC's so-called verified pharmacies. This includes (i) time responding to consumer inquiries, (ii) reviewing information provided by PCC on its main website and blog to consumers to effectively test those representations to determine whether and when to place those PCC sites on the "not-recommended sites" list, and (iii) maintaining the "not recommended sites list" in general as well as related literature to explain to consumers the danger of purchasing drugs via sites like PharmacyChecker.com or its so-called "verified" pharmacies.
- 263. The nature, quality, and characteristics of online pharmacy and of NABP and PCC are material to the purchasing public. PCC's false and misleading advertising and comparison is likely to, and indeed has, influenced consumer purchasing decisions. PCC has misled consumers into making purchasing decisions that expose themselves to significant legal and safety risks.
- D.C. who were connected to foreign pharmacies over of the time, and at least four D.C.

consumers were referred to and purchased from a PCC-accredited foreign pharmacy after clicking through PCC's website. Upon information and belief, there are additional D.C. consumers who purchased from one or more of PCC's affiliate pharmacies following a referral from PCC or a click from PCC's website.

- 265. Counterclaim-Plaintiff does not have an adequate remedy at law.
- 266. Counterclaim-Plaintiff has suffered damages in an amount exceeding \$75,000 proximately caused by Counterclaim-Defendant and is entitled to injunctive relief, actual, compensatory, and punitive damages to be determined at trial, disgorgement of Counterclaim-Defendant's profits, attorneys' fees, costs, and disbursements.

### **REQUEST FOR RELIEF**

WHEREFORE, NABP requests that this Court:

- A. Enter judgment against Counterclaim-Defendant;
- B. Declare that Counterclaim-Defendant's conduct violates D.C. Code §§ 28-3901 through 28-3913;
  - C. Enjoin Counterclaim-Defendant from continuing their unlawful acts;
- D. Award NABP compensatory, punitive, trebled, and other enhanced forms of damages, including, but not limited to, damages on a per-violation basis, reasonable attorney's fees, and other remedies as provided in D.C. Code § 28-3905(k)(2);
- E. Award NABP pre- and post- judgment interest at the applicable rates on all amounts awarded;
- F. Grant permanent injunctive relief to prevent the recurrence of the violations for which redress is sought in these Counterclaims; and
  - G. Order any other such relief as the Court deems appropriate.

# **DEMAND FOR JURY TRIAL**

Counterclaim-Plaintiff hereby demands a trial by jury on all claims.

Respectfully submitted,

Dated: October 20, 2022 Washington, D.C.

/s/ Erik T. Koons

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